AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

TRIM D21-9114

Response to the TGA on residual activity of disinfectants

Proposal 1: Definition of residual activity

The Regulations do not have a definition for residual activity. Currently, claims made for disinfectants are considered on a case-by-case basis. A potential definition of residual activity could be:

"The capability of a disinfectant product to continue to produce a reduction in the number of viable cells of relevant test organisms on a surface under use conditions defined on the label of the product."

RESPONSE:

The antimicrobial activity of a disinfectant is influenced by many factors, such as formulation, presence of an organic load, synergy, temperature, dilution and test methods[1], as well as how frequently the surfaces are touched.[2] Following this logic, it is likely that the residual activity of a disinfectant will also be impacted by these same factors.[3] The Australian Commission on Safety and Quality on Health Care (the Commission) recommends the definition for residual activity should also include boundaries around time. The Commission suggests the following additions and amendments, made in bold below, to the TGA's proposed definition:

"The capability of a disinfectant product to continue to produce a significant reduction in the number of viable cells of relevant test organisms on a surface ***after a specified period of time related to the conditions of use*** *defined on the product label."*

Proposal 2: Testing standards

For testing purposes, adopting the principles set out in PAS 2424:2014 Quantitative surface test for the evaluation of residual antimicrobial (bactericidal and/or yeasticidal) efficacy of liquid chemical disinfectants on hard non-porous surfaces – test method as a preferred methodology for demonstration of residual activity of disinfectants. It is recommended that additional guidance be developed to extend the test provisions to cover organisms other than bacteria or yeast, and periods of greater than 24 hours for residual activity.

RESPONSE

When testing for residual activity, it is important that appropriate test methods and test organisms are used and are consistent with the use of the disinfectants in practice. For example, the reduction of Gram-positive *Staphylococcus aureus* is relevant in hospital settings disinfectants, whereas reduction in Gram-negative *Salmonella enterica* serovar

Enteritidis is of relevance in food preparation facilities. Extension of the test requirements to cover other organisms not included in PAS 2424:2014 (e.g. viruses [SARS-CoV-2], other bacteria or fungi/moulds) should also be considered. Please note, the reference to PAS 2424:2014 in the supporting documentation was not accessible, therefore the defined conditions for the relevant test organisms in the residual activity definition are unclear.

The Commission agrees with the recommendation that additional guidance be developed to cover organisms other than bacteria or yeast, based on existing evidence that suggests there is variability in the effectiveness of disinfectants against different microorganisms.[1, 2]

The Commission supports that additional guidance be developed to extend the test provisions to cover for periods of residual activity greater than 24hours.

Proposal 3: Acceptance criteria

It is proposed that the acceptance criterion for a claim of residual activity be set at a 3-log difference between the test and the control.

RESPONSE

While a reduction of a 3-log difference between test and control is reasonable, it is also important to establish the reduction of organisms based on the direct effect of the disinfectant so that an overall reduction of 99.9% is considered effective. A study by Iniguez-Moreno, calculated the $\text{Percent reduction} = 100 - \frac{S(100)}{APC}$ where S is the surviving bacterial count (CFU/mL) and APC is the initial aerobic plate count (CFU/mL).[3] The disinfectant was considered to be effective when it demonstrated a bacterial reduction of 99.999%.[3] The Commission recommends this as a more suitable criteria for a claim of residual activity within a certain period of specified time, for each disinfectant tested.

Proposal 4: Limitations on claimed residual activity period

It is proposed that no limitations be placed on the period over which residual activity is claimed, as long as the claims are substantiated by test data.

RESPONSE

The Commission supports the proposal for no limitations to be placed on the period of a residual activity claim, regardless of whether such claims are substantiated by test data against relevant specific microorganisms. Claims on the period of time that disinfectants have residual activity may lead to a decrease in cleaning frequency and may have an impact patient and consumer safety. Claims on the period of residual activity are relevant to specific microorganisms whereas in practice, surfaces will be exposed to a multitude of organisms. Furthermore, claims on the period of residual activity will only be valid if the disinfected surface remains undisturbed.

Proposal 5: Restricting residual activity claims to specific organisms

It is proposed that residual activity claims can be made against general bacteria and/or specific organisms, if substantiated by test data.

RESPONSE

The Commission supports the position that only the specific microorganisms that were tested for the residual activity claim with substantiated test data can be addressed in a residual activity claim. Evidence exists that different antiseptics have varying antimicrobial activity against different microbes and there is also variability in the residual activity of antiseptics[4], so it is important that residual activity claims are made only for the specific microorganisms from the substantiated test data.

Proposal 6: Allowing residual activity claims

It is proposed that residual activity claims be allowed in the interim, and be assessed on a case by case basis. Should a test method or multiple test methods be defined, the new testing requirements will apply to new listings.

RESPONSE

In the absence of a standardised methodology for residual activity claims of disinfectants, the Commission supports assessing each claim on a case by case basis, which must be based on test data evidence. Tests should demonstrate the disinfectant maintaining a significant reduction in microbial numbers for a period of time. The Commission would support new test methods or multiple test methods that satisfy the new testing requirements.

References

1. McDonnell G, Russell AD. Antiseptics and disinfectants: activity, action, and resistance. Clin Microbiol Rev. 1999 Jan;12(1):147-179.
2. Tuladhar E, Hazeleger WC, Koopmans M, Zwietering MH, Beumer RR, Duizer E. Residual viral and bacterial contamination of surfaces after cleaning and disinfection. Appl Environ Microbiol. 2012 Nov;78(21):7769-7775.
3. Iniguez-Moreno M, Avila-Novoa MG, Gutierrez-Lomeli M. Resistance of pathogenic and spoilage microorganisms to disinfectants in the presence of organic matter and their residual effect on stainless steel and polypropylene. J Glob Antimicrob Resist. 2018 Sep;14:197-201.