

Good afternoon,

The Australian Commission on Safety and Quality is pleased to provide commentary on the TGA's Consultation Paper on residual claims for disinfectants - stakeholder consultation. I hope the following comments are of assistance:

a) The lack of a definition for residual activity

A clear definition of “residual activity” is required to specifically describe the scope of long-term disinfection claims. The following additions are suggested for consideration to the TGA's proposed definition:

*“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 **the specific** use conditions defined on the label of the product, **for a specified period of time.**”*

b) The lack of standardised testing standards for residual activity claims

In the absence of a standardised methodology for demonstration of residual activity of disinfectants, the Commission supports the adoption of the principles as 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*, with additional guidance on extension of the test requirements to cover organisms other than bacteria or yeast, and periods of greater than 24 hours for residual activity.

Additional guidance on extension of the test requirements to cover other organisms not included in PAS 2424:2014 (e.g. SARS-CoV-2, viruses, other bacteria or yeast) should also be considered.

This standard should only be applied to residual activity of liquid chemical disinfectants applied to non-porous hard surfaces. The principles set out in PAS 2424:2014 are not supported for adoption for non-liquid disinfectants, or disinfectants used for other purposes (i.e. porous surfaces, air).

c) The lack of acceptance criteria for residual activity claims

The Commission supports acceptance criterion for a claim of residual activity set:

- at a 3-log difference between the test and the control
- over a defined minimum dwell time
- under test conditions that mimic the practical conditions in which the product is designed to be used (i.e. in conjunction with physical/mechanical cleaning).

d) Whether there should be a limit on the period over which residual activity is claimed

The Commission supports the proposal that the period over which residual activity is claimed should be substantiated by test data against the specific microorganism/s. Claims of residual activity may lead to a decrease in cleaning frequency due to consumer perceptions and security, thus unsubstantiated claims could impact patient and consumer safety. Claims of residual activity are only valid if the disinfected surface remains undisturbed.

e) Whether residual activity claims should be restricted to general bacteria only and other specific organisms

The terms “general bacteria” and “other specific organisms” do not provide sufficient guidance, and need to be further defined. The Commission recommends that residual activity claims against any microorganism/s can only be made if substantiated by test data against that/those specific microorganism(s).

f) Whether residual activity claims should be disallowed until such time when the above could be clearly defined and resolved.

The Commission supports that, until such time as the aforementioned elements are defined and resolved, claims regarding residual activity in disinfectants should be disallowed.

If you have further enquiries, or the Commission can be of further assistance, please do not hesitate to contact me

Thanks you

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