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Submitted to **Proposal for clarifying regulatory requirements for residual claims for disinfectants**

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Introduction

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Dentalife Australia Pty Ltd

Proposal 1: Definition of residual activity

definition:

This definition is far too broad and obscure. I make this comment based on the variations in testing required for the different classes of organisms ie bacteria, viruses, fungi, etc.

The main issue is providing clear and precise information and instructions for users. The scope for misunderstanding and misuse of such a claim of "residual activity" in different environments ie clinics, hospitals, institutional and general public environments makes such claims irresponsible and misleading.

I don't believe you can define residual activity simply and clearly for the vast array of end-users.

I have been told by hospital officials that they would not accept a "residual claim" no matter what was approved.

Proposal 2: Testing standards

testing:

These could be developed but would have significant complexity.

There would need to be test methods (and standards) for liquid treatments and solid or particular treatments.

The problem is understanding and interpretation by the end user.

Proposal 3: Acceptance criteria

acceptance:

Why are you reducing the acceptance criterion below what is required for acceptance for kill time approvals?

Under this criteria residual activity does not provide the same level of risk mitigation of infection as kill time claims.

Surely, there has to be consistency or else understanding and safety are compromised.

Proposal 4: Limitations on claimed residual activity period

limitations:

The complexity of this aspect is in the form of the disinfectant ie standard liquid disinfectant that meets current TGO104 guidelines or a product formulated for specific residual activity.

Another issue is the area of application ie household bench top, a dental clinic bench top and a surgery table in a hospital operating theatre. These areas would have vastly different criteria for residual activity if the concept was accepted.

Proposal 5: Restricting residual activity claims to specific organisms

specific organisms:

This is a big unknown given how differently bacteria and viruses behave. Just as with TGO104 currently, there would have to be significantly different methods and acceptance criteria

Proposal 6: Allowing residual activity claims

allowing claims:

I totally disagree.

The concept is completely undefined currently and there is a risk of spreading infection at this time if these methods and acceptance criteria have not been through the same rigorous approval systems as the standards that have been accepted for the TGO104 guidelines.