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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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Organisation:
Reckitt Benckiser

Proposal 1: Definition of residual activity

definition:

The definition of residual activity of a disinfectant product must be consistent with the breadth of residual claims that the TGA intend to define a residual and therefore ‘specific claims’. As confirmed by the TGA (email) on the 22 Feb 2021, any and all residual claims including residual “bacteriostatic” claims are considered ‘specific claims’. This being the case, the proposed definition is not sufficiently broad to capture all residual claims. The proposed definition would exclude residual claims of a bacteriostatic nature, as such the alternative definition should be considered.

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

If the TGA are to consider any and all residual claims, including “bacteriostatic” residual claim as ‘specific claims’ then, consideration must also be given to appropriate methodologies and success criteria for such bacteriostatic claims. This has yet to be considered by the TGA, and therefore it is unclear what the TGA would consider as appropriate methodology and success criteria.

Alternatively, the RB preferred position, is to implement the definition as the TGA have proposed and to define residual bacteriostatic claims in line with non-residual bacteriostatic claims and treat these products as not regulated by the TGA. Additionally, exempt disinfectants making residual bacteriostatic claims should continue to be exempt disinfectants.

Proposal 2: Testing standards

testing:

RB support the use of methods such as PAS 2424 and the development of additional guidance to extend the test provisions to viruses and fungi. We would also like flexibility on number of hours for the residual claim, such that less than 24 hours can also be considered. Additionally, modifications to PAS 2424 should also be permitted to reducing the number of abrasions for applications where little or none occurs, which would be reflected in the directions for use and surfaces that the residual claim relates to.

RB also believes that the TGA should also permit other appropriate methodology such as the EPA Test Method for Residual Self -Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces. The acceptance of appropriate alternative methods allows Sponsors to leverage data generated to support overseas registrations and provide a harmonized approach.

Proposal 3: Acceptance criteria

acceptance:

RB is aligned with the TGA that a 3-log difference between the control and the treatment is appropriate. Additionally, this acceptance criteria should be used where the method is modified for viruses (with consideration for cytotoxicity).

RB also believes that the TGA should make this sufficiently clear in the guidance that many consumers are likely to believe that residual benefit will be achieved for the maximum period when “up to x days/hours” are claimed. The acceptance criteria (3-log difference) should therefore be met at for the maximum period claimed.

In addition to the above, if the TGA are to consider bacteriostatic residual claims as ‘specific claims’ then acceptance criteria for such claims also need to be set. The success criteria for this type of claim may include the average recovery on the test substance to be less than the recovery obtained from the non-active control.

Proposal 4: Limitations on claimed residual activity period

limitations:

The claimed period of residual activity should be consistent with the use directions and surfaces that the product is proposed to be use on. The period of residual claim will depend on the setting the product is to be used in and the surfaces listed on the labelling.
As such, the definition of terms like “multi touch” , “infrequently touched” or “high traffic areas” would help to identify the surfaces which are exposed for potential “contamination” (kitchen counters , bathroom counters , door knobs, light switches etc.) and will required a specific testing protocols to support these claims (e.g. efficacy confirmed after 4X inoculations per 24h can substantiate “multi-touch technology”). Defining such terms will also help provide consistency for both the TGA in approving claims and for consumers.

It is also RB view that excessive residual timeframes such as 30 and 365 days should not be permitted, especially within a consumer use context. The justification for the relevance to consumer use situations for such residual claims is not clear. Additionally it can be noted that PAS 2424 is not an acceptable methodology for these claims.

Proposal 5: Restricting residual activity claims to specific organisms

specific organisms:

It is RB view that residual claims against a spectrum of organisms (bacteria and viruses) should be permitted, as long as the data and test methods used support the claims being made. It would not benefit the consumer to restrict the activity to only select organisms. It can be noted that there are currently no known actives that give long lasting efficacy against non-enveloped viruses such as polio, adeno, noro. Current actives (such as bleach, ethanol) only give immediate efficacy, but due to their volatile nature they will not be present / potent after 24hrs, as such virus claims will naturally be limited to enveloped viruses and residual claims for viruses will be limited to those that data has been provided to support. The subsequent claim will therefore name the viruses tested.

Proposal 6: Allowing residual activity claims

allowing claims:

We support TGA’s current approach which allows the sponsor/manufacturer to formulate a test method to justify claims made, in instances where TGA has not delineated a required test method. Residual activity claims should continue to be allowed in the interim and be assessed on a case by case basis. Should a test method be later defined and required by TGA, such a method should apply to new products only, products already approved and marketed using different methods should be ‘grandfathered’ in and allowed to remain on the market indefinitely.