Consultation on residual claims for disinfectants

Accord is pleased to provide this submission to the TGA's consultation on residual claims for disinfectants.

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, personal care and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, cosmetic, personal care and specialty products, food contact sanitisers, industrial and agricultural sanitisers, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses. A list of Accord member companies is available on our website: http://accord.asn.au/about/members.

Members note that residual efficacy claims for disinfectants are especially relevant for high-touch surfaces such as door knobs, cupboard handles, lift buttons, taps, toilets, appliances, gym equipment etc. and are meaningful claims that are likely to guide product selection and usage habits of disinfectants in the household by consumers and also in healthcare settings, workplaces and public spaces by professional operators.

Residual activity claims should be substantiated with relevant quantitative data, be specific and meaningful in the effects they convey and also be consistent with current public health messaging (as required by the Therapeutic Goods Advertising Code (TGAC).

The current Government advice in the context of the COVID-19 pandemic directs the public to regularly clean and disinfect frequently touched surfaces in the home while workplaces and healthcare settings are encouraged to carry out at least daily cleaning and disinfection. Claims for residual activity of disinfectants should be considered in the context of the current public health advice and should not encourage behaviour that is inconsistent with this messaging such as less frequent cleaning and disinfecting.

Sections 9 and 10 of the TGAC also contain several provisions which may relate to the appropriateness (or otherwise) of residual efficacy claims on disinfectant products, such as:

Advertising for therapeutic goods must:
(a) support the safe and proper use of therapeutic goods by:
(i) presenting the goods in accordance with directions or instructions for use; and
(ii) not exaggerating product efficacy or performance;

As a new aspect of the disinfectants area, we would encourage the TGA to not only update the relevant provisions of TGO 104 and the TGA Instructions for Testing, but also ensure that all of the associated guidance including, Disinfectant Claim Guide etc. are also updated to provide practical guidance to industry on allowed claims and the test method(s) required to substantiate those claims.

We would also appreciate guidance as to when residual claims would be considered specific claims, and therefore require evaluation by the TGA. For example, would lower level residual claims against general bacteria require a product that would otherwise be Exempt to be Listed? Or would evaluation by the TGA be required only when the residual claims refer to specific bacteria or viruses?

We are happy to assist in the development of such guidance and examples to ensure they are relevant to industry products and practices.

We have included below specific comments to each of the TGA proposals:

1. **The definition of residual activity of a disinfectant product as:**
   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.

Accord members support this proposal. We also note that it is in line with the current EU definition.

2. **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. As the PAS is subject to copyright, it is recommended that it be adopted as is, with additional guidance on extension of the test provisions to cover organisms other than bacteria or yeast, and periods of greater than 24 hours for residual activity.**

Accord members support this proposal.

In addition, the US EPA Protocol #01-1A, “Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard, Non-Porous Surfaces” (attached) is also proposed for inclusion as a preferred methodology for demonstration of residual activity of disinfectants. Although it’s called a sanitiser method, in the US it is also used in conjunction with disinfectant testing for residual activity claims on disinfectants.

We note that both the PAS and the US EPA protocols are designed to test disinfectants on hard, non-porous surfaces, so would not be directly applicable for disinfectants intended for use on fabrics/textiles including clothing and upholstery (such as office chairs, public transport etc.). We would appreciate the TGA’s guidance in relation to residual claims for disinfectants intended for use on “soft” surfaces.

While specifying preferred methodology will provide valuable guidance and clarity for industry, the acceptance of any other valid alternative methodology presented should also continue on a case-by-case basis.

We understand that the methodology described in PAS 2424.2014 is widely accepted around the world and aligns with the typical US EPA registration method for hard surface disinfectants. We also understand that Australian testing laboratories have the capacity to undertake testing in line with the principles of this methodology, so local testing will be accessible.

Key aspects of any acceptable methodology must address not only applying the product and letting it sit for a period of time, but also to stress the treated surface with abrasions that mimic the real-world pressures those surfaces would face. This helps build robustness in the efficacy profile of a disinfectant and distinguishes those formulations that can perhaps remain stable when dried onto a surface from those that will persist and remain efficacious despite routine touch points.

Members have indicated that additional guidance on extension of the test provisions to cover organisms other than bacteria or yeast, and periods of greater than 24 hours for residual activity would be useful, in particular addressing the specific bacteria or virus strains which should be tested in order to support broader claims.

3. The acceptance criterion for a claim of residual activity should be set at a 3-log difference between the test and the control.

Accord members support this proposal.

4. The period over which residual activity is claimed has to be substantiated by test data.

Accord members support this proposal.

Claims around the time period of residual activity must be substantiated by test data, and also be expressed in terms specific enough so as not leave any ambiguity around the level of efficacy and performance of the disinfectant that can be expected in practice when the product is used in accordance with the directions for use. Unqualified claims regarding the period of residual activity such as “long-lasting protection” and “extended period of time” have the potential to mislead users of the products and are therefore not supported.

The claimed period of residual activity should also be consistent with the use directions of the product, including the settings of use (household vs non-household) and the types of surfaces that the product is proposed to be used on. The test methodology should accurately reflect the relevant wear/touch profile expected for those uses.

Where claims include a period of “up to x days/hours” it should be clear that the test data must demonstrate that the acceptance criteria is met up to and including the maximum period claimed.

The appropriateness of residual activity claims over longer time periods should also be considered in the context of the Therapeutic Goods Advertising Code, including current public health messaging (as mentioned above).

5. Residual activity claims can be made against general bacteria and/or specific organisms, if substantiated by test data.

Accord members support this proposal.