Australian Government
Department of Health
Therapeutic Goods Administration

Proposal for clarifying regulatory requirements for residual claims for disinfectants

Stakeholder consultation

Version 3.0, March 2021

TGA Health Safety Regulation

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Introduction

This consultation is to obtain feedback in relation to proposals to provide clarity on residual claims for disinfectants.

The Therapeutic Goods Administration (TGA) has received a number of enquiries relating to residual activity claims for disinfectants, including whether statements can be made for disinfectants such as 'residual activity for up to 30 days', and what testing methods should be used to provide evidence for these claims.

At present, there is no definition of "residual activity" included in the *Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) 2019* (the Order) or the TGA published guidance document: *TGA Instructions for Disinfectant Testing*. There are also no defined test methods or specified acceptance criteria for such testing. To date, claims have been considered (and continue to be considered) by the TGA assessors on a case by case basis. The approach we have taken is that the sponsor/manufacturer should formulate a test method to justify the claims they wish to make. Any sponsor/manufacturer of a disinfectant product can make an application to list a product in the Australian Register of Therapeutic Goods (ARTG) including claims of "residual activity" if they have test methods and data to justify the claims.

Guidance to date on residual claims has been in part informed by the Publicly Available Specification (PAS) published by the British Standards Institute, which defines good practice standards for disinfectants (PAS 2424:2014).

We are seeking feedback on the following:

1. A definition of residual activity of a disinfectant product
2. Testing standards for residual activity claims
3. Acceptance criteria for residual activity claims
4. Whether there should be a limit on the period over which residual activity is claimed
5. Whether residual activity claims should be restricted to general bacteria only and other specific organisms
6. Whether residual activity claims should be disallowed.

Feedback from the Consultation Paper may inform changes to the regulatory framework, including the TGO 104 or other accompanying documentation relating to disinfectants.

Background

Disinfectants that make specific claims are 'Listed disinfectants' and are required to be listed in the Australian Register of Therapeutic Goods (ARTG) before they are supplied to the market. These disinfectants must meet all regulatory requirements as set out in the relevant legislation and guidance and must have available evidence to substantiate any claims.

Before a specific claim can be made on a product, labelling or consumer advertising that a disinfectant has an effect against any virus, permission must be sought from the TGA to make that claim.

In response to the COVID-19 pandemic, a large number of applications were received by the TGA for listed hospital or household/commercial disinfectants. These applications sought to make claims for efficacy against COVID-19, with some products claiming to provide residual activity. Due to lack of guidance around claims for residual activity, many claims remain ambiguous as to what protection the products may provide and whether such claims may be considered acceptable. Some examples of recent claims for residual activity include:

- “forms a protective polymer to provide residual bacteriostatic efficacy on high-touch surfaces for up to 24 hours and on low-touch surfaces for up to 30 days”
- “long lasting residual antimicrobial activity for up to 30 days. Up to 200 touch and moisture resistant”
- “residual COVID-19 kill for up to 7 days”
- “long acting protectant which uses self-assembling polymers to form a residual, active coating proven to be effective against a broad range of bacteria and fungus”
- “uses self-assembling polymers to form a residual, active coating against a broad range of bacteria and COVID-19 for extended periods of time (even after standard cleaning practices)”
- “provides sustainable protection for up to 365 days”

Proposal Discussion

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.*

Discussion

The Publicly Available Specification (PAS) is a fast-track standardization document, the result of an expert consulting service from the British Standards Institute, which defines good practice standards for a product, service or process. It is developed by a steering group of stakeholders, selected from relevant fields and led by BSI.

The 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* defines residual bactericidal/yeasticidal activity as:

The capability of a product to continue to produce a reduction in the number of viable bacteria/yeast cells of relevant test organisms under conditions defined in this PAS.

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.

Discussion

To date, the TGA has allowed the sponsor/manufacturer to formulate a test method to justify the claims made. In applications made to the TGA, there have been a range of examples of testing methods based on:

- BS EN 13697 Chemical disinfectants and antiseptics, Quantitative non- porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements without mechanical action (phase 2, step 2). The standard method was modified by first spraying the test surface with the product, storing the treated surfaces for the labelled residual period (for example 30 days) and then inoculating the surface with the test bacteria and testing for surviving organisms after a dwell period. The usual process for EN 13697 is to dry the required starting inoculum onto the surface of the test disk and then apply the disinfectant for the required contact time. In order to test a surface bound antimicrobial the process is 'inverted' (that is, the inoculum is applied to the disinfectant surface vs applying the disinfectant to the inoculum).

- EN 16777:2018 Chemical disinfectants and antiseptics. Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area. Test method and requirements (phase 2/step 2), possibly similar to the testing adapted from EN 13697.

- ASTM method and a provisional European standard for evaluation of residual activity (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). Details however of the method were not provided, other than to apply product and allow the surface to dry for required period of stated residual activity, then inoculate with virus and leave for required contact time, then test for residual virus.

- a claim of residual antimicrobial efficacy for 30 days against Staph aureus and E coli, for residual activity after 12 months. In the method used, various test surfaces were sprayed with disinfectant and stored for required period. Treated surfaces were then placed onto agar plates seeded with bacteria and the zones of inhibition noted.

There have been no examples in the applications made to TGA that include test data to support the claims of residual activity after a number of "touches".

The PAS contains the only known published relevant testing method (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.

PAS 2424:2014 specifies a test method for the residual bactericidal and/or yeasticidal activity of liquid chemical disinfectant products that are applied to hard, non-porous surfaces likely to undergo abrasive action. The test remains as close as possible to the practical conditions in which the product is designed to be used by taking into consideration both abrasion and spillage. It quotes research which found that once a disinfectant is applied to a surface in normal household use, the surface is subject to continual abrasion, such as touching and wiping, and that disinfectant application is likely to occur every 24 hours.

> The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used. It is intended to provide a rigorous and credible test that enables residual antimicrobial activity to be independently measured and assessed in a way that is more relevant to how these products are used outside the laboratory.

The method involves applying an initial inoculation of organisms to a steel disc, and allowing it to dry. The surface is then treated with the product under test and the surface allowed to dry again. Over a period of 24 hours, the surface is exposed to a series of abrasion cycles (using a folded wipe) and re-inoculations, simulating in-use conditions of wiping and touch. After 24 hours, the disc is exposed to a final inoculation cycle under defined conditions and defined contact time. The disc then undergoes a neutralisation step, to nullify any residual disinfectant activity, and the number of surviving organisms calculated. A disc treated with hard water rather than disinfectant is used as a control, and the reduction in viable organisms as a result of the residual product is calculated by the difference between the discs. A product with acceptable residual activity is expected to show a 3-log difference after 24 hours.

The results will be accepted only after initial testing of the disinfectant has been conducted and found acceptable in accordance with EN 13697 *Chemical disinfectants and antiseptics, Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements without mechanical action (phase 2, step 2).*

Although the method is intended to show residual bactericidal or yeasticidal activity after 24 hours only, it could be adapted to demonstrate residual activity for viruses and other micro-organisms over longer time periods. The PAS allows that additional test conditions may be necessary dependent upon the intended use of the product under test.

The evidence for residual activity should reflect the claims for activity on the label. It could be considered misleading to claim a spectrum of activity (for example, bactericidal, fungicidal, virucidal activity) on the label, if testing for residual activity covers bacteria only.

In considering claims of residual activity over a period of time (e.g. 30 days), consideration has to be made with regard to consumer perceptions and the sense of security created through such claims, particularly during periods of infectious outbreaks, and whether guidelines or time limitations would be required.

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.

Discussion

Note that a 3-log reduction in the virucidal test is sufficient to claim efficacy against that virus if cytotoxicity is present, which is a better claim than residual activity. For a residual claim against viruses, it therefore appears that the requirements are not equivalent to that for bacteria, noting that bactericidal efficacy requires a 6-log reduction, but only a 3-log reduction for residual activity. Therefore, a potentially higher standard is applied to residual claims for viruses compared to bacteria. Feedback is sought on whether a 3-log reduction for residual claims against viruses is reasonable given the acceptance criteria applied to the testing for virucidal activity.

Proposal 4: Limitations on claimed residual activity period

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

Discussion

To date, the TGA has not limited the period over which residual activity is claimed, as long as the claim is substantiated by test data, noting that claims have mostly been for up to 30 days. Further, a number of applications have been received with claims of residual activity under 'high touch' and 'low touch' conditions over a period of time (e.g. 30 days).

Feedback is sought on whether a limit should be placed on the period over which residual activity is claimed, and whether claims of 'high touch' / 'low touch' conditions and the like should be allowed in conjunction with the residual activity period.

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.

Discussion

Some specific organisms are highly pathogenic, which may justify a case for not allowing residual claims for such organisms. However, it is noted that there are also general bacteria that are highly pathogenic. Feedback is therefore sought on whether residual activity claims should be restricted to specific organisms.

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.

Discussion

The approach we have adopted to date is that the sponsor/manufacturer should formulate a test method to justify the claims made. Feedback is sought on whether residual activity claims should continue to be allowed in the interim, and be assessed on a case by case basis, and whether the test methods, when defined, is applied only to new listings and not retrospectively to previously listed disinfectants.

What we invite you to do

In your submission, we ask you to consider the proposals outlined above and provide any comments or feedback as to whether these proposals will help clarify requirements for the regulation of disinfectants that make residual claims.

How to submit your feedback

You can submit your feedback using our **online survey tool**
https://consultations.health.gov.au/tga/disinfectants-residual-claims

Please direct any queries via email to devicereforms@tga.gov.au.

This survey closes at 5pm on 26 March 2021

Version history

Version	Description of change	Author	Effective date
V1.0	Original draft consultation for limited consultation	Medical Devices Branch	September 2020
V2.0	Updated Introduction section and What we invite you to do section; minor updates to other sections.	Medical Devices Branch	February 2021

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