RE: RESIDUAL DISINFECTANT CLAIMS UNDER TGA REGULATIONS

No residual claim (virucidal or otherwise) is allowed on a disinfectant under TGA Regulations

Verification

1. All TGA disinfectants must meet the performance requirements of the Therapeutic Goods Order 104 **(Therapeutic Goods (Standard for Disinfectants and Sanitary Products) (TGO 104) Order 2019**, https://www.legislation.gov.au/Details/F2019L00482)

2. The TGO 104 specifies that all disinfectants must pass the appropriate test as specified in Division 2, part 2 of the Instructions (**TGA instructions for disinfectant testing Version 2.1, March 2020** https://www.tga.gov.au/publication/tga-instructions-disinfectant-testing)

3. These Instructions mandate the following requirements for an appropriate test
   - All tests should be carried out by a GMP licensed laboratory or laboratory accredited to ISO/IEC 17025 or equivalent, e.g. NATA, TGA, US FDA, PIC/S, US EPA, NAMAS UK etc.
   - Test methods must be validated by individual laboratories for each test method used in accordance with tests which have been validated or refereed at national or international level
   - Disinfectants claiming bactericidal efficacy MUST pass Option B of the TGA Disinfectant Test under dirty conditions. This is a semi-quantitative suspension test. Testing in accordance with the dirty conditions option of EN 13727[4] will also be accepted. Other suspension tests may be acceptable if modified to include 5% organic soil and water of minimum hardness >340ppm.
   - These disinfectants MUST also pass a bactericidal carrier test. AOAC methodology (60 carriers per organism) or equivalent method, such as ASTM E2197 or ASTM E2111 may be used. Testing conducted in accordance with EN 14561 or EN 13697 will be accepted if modified to use 60 carriers per test organism.

4. Virucidal claims are known as specific claims (**Disinfectant Claim Guide - specific claims and non-specific claims** https://www.tga.gov.au/publication/disinfectant-claim-guide-specific-claims-and-non-specific-claims). Products that make specific claims are required to be Listed in the ARTG prior to their supply. The testing set out in the TGA instructions for disinfectant testing must be conducted to validate specific claims.
   - When specific biocidal claims are made (i.e., virucidal, fungicidal, tuberculocidal, sporicidal, or other biocidal activity), the disinfectant must pass appropriate tests as specified below.
   - All test should be carried out using the exposure time, temperature and pH specified on the label. For products intended for use on surfaces that have not been pre-cleaned, 5% organic soil must be included.
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- For a general virucidal claim, not including blood borne viruses such as HIV, HBV, HCV, Ebola etc., the disinfectant MUST pass tests, using Poliovirus/Parvovirus and Herpes simplex as the test viruses.
- The tests may be suspension tests but carrier tests are preferred. Methods that may be used as a basis are the AOAC Use Dilution Test modified for viruses and ASTM E2197. One surface is required to be tested for each of two batches of product. Guidance on carrier test methodology is provided in ASTM E 1053[13]. Guidance on suspension test methodology is provided in ASTM E 1052[14]: *Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension*. If a suspension test is used, the methodology of EN 14476 is acceptable.
- Tests on the designated prototype viruses should be performed in quadruplicate against a recoverable viral titre of at least 4-$\log_{10}$, which must be recoverable from the test surface or suspension, and should show complete viral inactivation.
- For claims against SARS or COVID-19, Human coronavirus 229E or Murine hepatitis virus can be used as a surrogate if either the SARS virus or the COVID-19 virus cannot be used.

Summary:

All disinfectants claiming bactericidal, virucidal, fungicidal or other efficacy must comply with the Therapeutic Goods Act, and must meet the requirements of the relevant Therapeutic Goods Order 104

https://www.legislation.gov.au/Details/F2019L00482

Both Residual and Virucidal claims are specific claims under TGA legislation

https://www.tga.gov.au/publication/disinfectant-claim-guide-specific-claims-and-non-specific-claims

Specific claims can only be made when tested according to approved TGA protocols, and must be approved by the TGA

https://www.tga.gov.au/publication/tga-instructions-disinfectant-testing

There are no TGA approved protocols for Residual Activity, therefore any residual activity claims are not TGA approved. Any company claiming residual disinfection is in breach of the Therapeutic Goods Act. Any business promoting such products are also in breach of the Act.

There are no TGA approved protocols for Residual Virucidal Activity, therefore any virucidal residual activity claims are not TGA approved. Any company claiming residual virucidal efficacy is in breach of the Therapeutic Goods Act. Any business promoting such products are also in breach of the Act.

If a product makes a Residual and/or Virucidal claim they **must** produce the TGA Listed Register Entry that shows **this claim has been approved by the TGA**.