Australian Government
Department of Health
Therapeutic Goods Administration

Surrogate viruses for use in disinfectant efficacy tests to justify claims against COVID-19

7 May 2020

For sponsors and manufacturers wishing to make label claims of efficacy against COVID-19 for products that are either hard surface disinfectants or disinfectants that are medical devices, the following surrogate viruses can be used:

- Human coronavirus 229E
- Murine hepatitis virus

In the event that either Human coronavirus 229E or Murine hepatitis virus cannot be used, consideration will be given to use of other human or animal coronaviruses. Viruses that have been suggested include Bovine coronavirus and Feline coronavirus.

If coronaviruses other than the specified surrogates are to be used, contact Leisa Whitby (mailto:Leisa.Whitby@health.gov.au) or call 02 6289 2309.

Frequently asked questions

The TGA has received several enquiries from disinfectant sponsors and manufacturers wishing to make specific label claims for efficacy against COVID-19.

Here is a list of commonly asked questions.

Which surrogates are allowed for use to justify a COVID-19 efficacy claim?

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The following surrogate viruses can be used:

- Human coronavirus 229E
- Murine hepatitis virus.

As outlined above, if Human coronavirus 229E or Murine hepatitis virus cannot be used, consideration will be given on a case-by-case basis to the use of other human or animal coronaviruses, with an appropriate justification. Viruses that have been suggested include Bovine coronavirus and Feline coronavirus.

Can I use a virus other than a coronavirus to justify a COVID-19 claim?

No. Viruses other than those that are coronaviruses cannot be used to justify label claims against COVID-19 for hard surface disinfectants and disinfectants that are medical devices.

How do I know that a test method is appropriate?

For hard surface disinfectants, details of the testing required are found in the TGA instructions for disinfectant testing (//www.tga.gov.au/publication/tga-instructions-disinfectant-testing) under Part 2, Division 2: *Specific tests for hospital grade disinfectants and household/commercial grade disinfectants - Virucidal testing*.

For disinfectants that are medical devices, details can be found in the Guidelines for the evaluation of sterilants and disinfectants (//www.tga.gov.au/publication/guidelines-evaluation-sterilants-and-disinfectants) in Section 6.4.5 *Virucidal tests*.

How do I know if a laboratory is suitable to perform this testing?

All tests should be carried out by a GMP licensed laboratory or laboratory accredited to ISO/IEC 17025 or equivalent, such as (but not limited to) NATA, TGA, US FDA, PIC/S, US EPA, or UKAS. If requested, statements assuring adherence to Good Laboratory Practice (GLP) should be provided.

How do I make an application to list or include a disinfectant on the Australian Register of Therapeutic Goods (ARTG) that has a COVID-19 specific claim on the label?

Hard surface disinfectants and disinfectants that are medical devices are regulated by the Medical Devices Authorisation Branch (MDAB) of the TGA. Hard surface disinfectants are regulated as 'Other therapeutic goods', and disinfectants that are intended to be used on medical devices are regulated as medical devices.

Hard surface disinfectants with a label claim against COVID-19 (or a claim against viruses, spores, tuberculosis, mycobacteria or fungi) must be listed on the ARTG; therefore, an application for listing must be made. Refer to Guidance on the regulation of listed disinfectants in Australia (//www.tga.gov.au/publication/guidance-regulation-listed-disinfectants-australia) for more information.

For disinfectants that are medical devices, an application for inclusion on the ARTG (//www.tga.gov.au/publication/medical-device-inclusion-process) must be made.

On 24 April 2020, the TGA issued legal permission for specified disinfectants to include claims of efficacy against SARS-CoV-2, which had previously been a prohibited representation. The Permission (//www.tga.gov.au/advert-exempt/therapeutic-goods-prohibited-representations-disinfectants-covid-19-permission-2020) can be found on the TGA website.

You should ensure that you have all the data that you need to support your proposed COVID-19 claim or any other specific claims that you wish to make. Please note that the TGA does not provide a pre-evaluation service.

If you have any questions about applications for disinfectants, contact the Medical Device Information Service at devices@tga.gov.au (mailto:devices@tga.gov.au) or 1800 141 144.

What if my product is already on the ARTG and I want to include a COVID-19 specific claim on the label?

For hard surface disinfectants and disinfectants that are medical devices, a Device Change Request application must be made.

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