

Notice to Stakeholders: Indirect Claims of Disinfectant Drug Efficacy against the Monkeypox Virus

Health Canada has an emerging viral pathogens approach for disinfectant drugs which have received market authorization, as indicated within Appendix 12, Section 5 of the *Guidance document - Safety and Efficacy Requirements for Surface Disinfectant Drugs 2020* (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/summary.html#s2>), hereafter referred to as Safety and Efficacy guidance for disinfectants.

The backbone of Health Canada’s emerging viral pathogens approach is Health Canada’s “broad spectrum virucide” claim, which is defined as:

Broad-spectrum virucide: *A substance, or mixture of substances, capable of destroying or irreversibly inactivating at a minimum one representative hard to kill non-enveloped virus, and which is expected to inactivate other enveloped and non-enveloped viruses present on environmental surfaces and inanimate objects¹.*

As detailed within the Safety and Efficacy guidance for disinfectants, Health Canada’s emerging viral pathogens approach is applicable once ONE of the following triggers has been met:

- Public Health Agency of Canada (PHAC) has issued a public notice that an emerging viral pathogen poses a significant risk to Canadians; OR
- World Health Organization (WHO) having declared an emerging virus as a public health emergency of international concern (PHEIC).

Once at least ONE of the above triggers has been met, Health Canada will permit manufacturers to provide communications to the public regarding the expected efficacy of certain authorized disinfectant drugs against the emerging viral pathogen: this includes communications through their web sites, toll free consumer information services, and similar media.

As detailed within the Safety and Efficacy guidance for disinfectants, there are efficacy criteria that must be met in order for such communications to be made, and if these are not met, then the indirect claims are considered to be unsubstantiated.

The WHO has declared the monkeypox outbreak to be a public health emergency of international concern (PHEIC), effective July 23, 2022. Monkeypox viruses are enveloped viruses, meaning they are one of the easiest to kill with an appropriate disinfectant product compared to non-enveloped viruses, and belong to the *Poxviridae* family, part of the same family of viruses as variola virus, the virus that causes smallpox.

Because non-enveloped viruses are more resistant to surface disinfectants than enveloped viruses, surface disinfectants that are effective against non-enveloped viruses are expected to also be effective against enveloped viruses. Therefore, only drug identification number (DIN)-authorized disinfectants with approved claims as either a “broad spectrum virucide” or with a specific claim against a non-enveloped virus will be permitted to make indirect efficacy claims against the monkeypox virus.

¹ *Guidance Document - Disinfectant Drugs* (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/summary.html#s2>)

Examples of non-enveloped viruses are adenovirus type 5, bovine parvovirus, canine parvovirus, and poliovirus type 1).

For disinfectant drugs that have received market authorization, note that **ONLY** indirect claims are permitted for the monkeypox virus, such as “expected to be effective” and “likely to be effective”. Direct claims against the monkeypox virus **CANNOT** be made. The following are examples of acceptable wording for indirect communications related to monkeypox:

- "DIN-approved disinfectants which have received market authorization for a "broad spectrum virucide" claim (i.e., have proven efficacy against a hard-to-kill non-enveloped virus) or a specific claim against a non-enveloped virus are expected to inactivate less resistant enveloped viruses, such as monkeypox. Therefore, in choosing a hard surface disinfectant to be used against monkeypox, any disinfectant with a "broad spectrum virucide" claim or a specific claim against a non-enveloped virus would be appropriate, as it would be expected to also inactivate the monkeypox virus."
- “This product (insert Product Name) is a broad-spectrum virucidal hard surface disinfectant that is expected to inactivate the monkeypox virus”.
- “Kills (insert surrogate virus name) and is likely to kill the monkeypox virus”.
- “Effective against (insert surrogate virus name) and likely to kill the monkeypox virus.”
- “This product has demonstrated effectiveness against (insert surrogate virus name) and is expected to inactivate the monkeypox virus.”

Given that the poxviruses show extraordinary resistance to drying, and increased temperature and pH tolerance when compared with other enveloped viruses, Health Canada will not permit the use of an approved efficacy claim against a virus within the same taxonomic genus to support indirect claims against the monkeypox virus. However, this position may change should further scientific information become available.

For further information regarding Health Canada’s emerging viral pathogens approach for disinfectant drugs, please contact the Natural and Non-prescription Health Products Directorate (NNHPD) via e-mail at hc.nnhpd-dpsnso.sc@canada.ca.