



Understanding Devices and Residual Claims

During the ongoing pandemic, there has been an increase in pesticide products across the United States that claim residual efficacy to address SARS-CoV-2. The EPA will focus on ensuring compliance with requirements applicable to these products to ensure protection of public health.

https://www.epa.gov/coronavirus/will-epa-take-enforcement-action-against-companies-making-false-claims-their

There are residual claims stated on products, meaning there is a claim of residual antimicrobial activity that continues after treatment. These apply to bacteria, as allowed with supporting test data by the EPA. At this time, there are no residual virucidal claims allowed by the EPA.

The EPA has published <u>List N</u> for disinfectants for use against SARS-CoV-2. These product meet the EPA's criteria for use against this virus that causes COVID-19. The products on List N do not include any residual claims against SARS-CoV-2.

We suggest that the following questions be considered when reviewing product claims:

Q: Is the disinfectant or sanitizer registered with the EPA?

A: To be considered a disinfectant or sanitizer, the chemistry should be registered as such with the EPA as a pesticide. The registration number can be looked up here for the most current label.

https://iaspub.epa.gov/apex/pesticides/f?p=113:1:::NO:RP,1,2::

Q: If a device is registered with the EPA, can it be a pesticide?

A: If the product is an instrument or contrivance and claims to control pests through physical or mechanical means, the product is considered to be a device, unless it is a firearm. Unlike registrants of pesticide products, FIFRA does not require device producers to submit any data concerning either safety or efficacy of a device prior to distribution or sale. This is particularly important to note for antimicrobial pesticide devices that claim to disinfect, sanitize, and/or sterilize items or ambient air. Because microbial pests are not visible to the naked eye, users of such devices generally cannot evaluate the actual performance of the device. The device may be "misbranded" if labels, labeling, and/or websites for devices, including general or specific efficacy claims, include any statement, design, or graphic representation that is "false or misleading in any particular." Distribution or sale of a misbranded device is prohibited under FIFRA. Therefore, every producer or seller of devices is responsible for ensuring that these products perform as claimed, and that such performance claims are not misleading to the intended user.

https://www.epa.gov/safepestcontrol/pesticide-devices-guide-consumers#4

Q. Does EPA permit claims for residual activity?

A: Yes, the EPA has a Protocol for Residual Self-Sanitizing Activity of Dried Chemical Residues on hard, non-porous surfaces, for bacteria species, not viruses.



https://www.epa.gov/pesticide-registration/protocol-residual-self-sanitizing-activity-dried-chemical-residues-hard-non

- This protocol is limited to sanitizer, not disinfectant claims and only
- Pertains to bacteria, specifically those noted on the EPA label

Q: Is there a product which claims residual activity against viruses or specifically SARS-CoV-2?

A: There is no EPA registered product with a SARS-CoV-2 residual claim, nor does the EPA Residual method permit virucidal claims. The only products approved by the EPA are the products on List N, Disinfectants for Use Against SARS-CoV-2. The products on List N do not include any residual claims against SARS-CoV-2.

https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

Q: What is a treated article?

A: A treated article is one that has been treated with an antimicrobial or pesticide. It is actually just a treatment to protect the article itself with non-public health claims. It does not provide disinfection to environmental surfaces.

Q. How are products treated with pesticides regulated?

A. Articles or products that claim to be effective in controlling microorganisms such as E. coli, S. aureus, Salmonella sp. or Streptococcus sp. must be registered as a pesticide. These articles or products make a public health claim that goes beyond the preservation of the treated article itself. EPA requires the submission of chemical data in support of the public health labeling claims and patterns of use of the product.

Any pesticide-treated product that is not registered by EPA must not make public health claims, such as "fights germs, provides antibacterial protection, or controls fungus." EPA's policy is predicated on the fact that no scientific evidence exists that these products prevent the spread of germs and harmful microorganisms in humans.

Q: Is there a difference in Public Health Claim vs Non-public Health Claim?

A: Public health claims are those that go beyond the preservation of the treated article and have been registered with the EPA with the supporting data. Non-public health are those that do not protect users but the article treated. The EPA agency generally does not require submission of efficacy data to support such claims (40 CFR § 158.2220(a)(3)).

Q: What does it mean if the label has a Bacteriostatic or Fungistatic Claim?

A: Bacteriostatic and Fungistatic claims demonstrate inhibition of bacteria or fungi and do not indicate the surface has been disinfected. Static claims do not apply to viruses.



Q: <u>Can EPA take enforcement action against companies making false claims that their disinfectants work against SARS-CoV-2?</u>

https://www.epa.gov/coronavirus/will-epa-take-enforcement-action-against-companies-making-false-claims-their

A: Yes, EPA is authorized to take enforcement action to prevent the sale or distribution of disinfectants with false or misleading claims on their labeling. EPA is also authorized to take enforcement action to prevent the sale or distribution of unregistered disinfectants when the seller or distributor is making claims that they work against SARS-CoV-2, and to prevent the sale or distribution of registered pesticides that are not permitted to make SARS-CoV-2 claims by the terms of their registration.