



Understanding Regulation Differences between Devices and Formulated Chemical Disinfectants

Tech Talk

This Tech Talk is based on the regulatory framework for devices and formulated chemical products that make disinfectant claims for non-critical surfaces in the United States, which may vary from requirements in other countries. Local regulations should always be consulted when evaluating disinfectant claims outside of the U.S.

EPA Regulation

In the U.S., pesticide products are regulated by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and include antimicrobials like formulated chemical disinfectants that are applied on non-critical surfaces (surfaces that only contact intact skin). Formulated chemical disinfectant substances are approved by the EPA after acceptable data on product performance (effectiveness), toxicological effects, ecological effects, ecological fate and chemistry is submitted for them. EPA-approved disinfectants are granted an EPA Registration Number, which must then appear on the product label. In addition to that, EPA approves a final label with the recommendation of use for these products.

The EPA also regulates devices used to control pests like bacteria – which can include equipment that generates UV light, or water systems that generate ozone – if antimicrobial (sanitizing or disinfecting) claims are being made. However, these devices are not required to be registered at the EPA federal level, as that regulatory approval framework is applied only for formulated chemical substances. Some states do require device registrations, but that process does not involve proof of efficacy.

EPA Labeling

However, devices are subject to certain labeling requirements, according to FIFRA and those states requiring devices be registered, and one of them is to have an EPA Establishment Number where the device was manufactured. Like formulated chemical disinfectant substances, pesticide devices are required to show that EPA Establishment Number on the label. Users of these devices might misinterpret the EPA Est. No. to mean EPA Registration, and so may be under the impression that they are EPA approved (registered) as sanitizers or disinfectants.

More information can be found at <http://www.epa.gov/pesticides/factsheets/devices.htm>

EPA Approval

Pesticide devices that make antimicrobial (bacterial kill) claims, like UV light and water-ozone systems, are not required to be EPA approved because that process is only for formulated chemical disinfectant substances. Therefore, they are not required to present any efficacy proof for the EPA's review for a final label. The EPA

Since the EPA does not require proof of effectiveness for devices, manufacturers have the responsibility of evaluating effectiveness. However, manufacturer efficacy data also needs to be reviewed by the end user to determine whether it translates to effectiveness for their specific applications.

Registration process for chemical disinfectants requires proof of effectiveness be demonstrated to the EPA before approval is granted. Since the EPA does not require proof of effectiveness for devices, manufacturers have the responsibility of evaluating effectiveness. However, manufacturer efficacy data also needs to be reviewed by the end user to determine whether it translates to effectiveness for their specific applications. Devices can have transient and variable effectiveness and the data provided by the device manufacturer should be carefully scrutinized for scientific validity and to determine whether it truly translates to infection risk reduction in the end-users application.

In general, the CDC recommends EPA Registered Disinfectants for non-critical surface disinfection, and only briefly mentions devices in their Guidelines, mainly for applications other than surface disinfection.

References

- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 CDC HICPAC Committee
- EPA DIS/TSS Guidance Documents, Disinfectant Technical Science Section, EPA Office of Pesticide Programs

Notice to Reader

The technical information, recommendations and other statements contained in this document are based upon tests or experience that 3M believes are reliable, but the accuracy or completeness of such information is not guaranteed. Many factors beyond 3M's control and uniquely within the user's knowledge and control can affect the use and performance of a 3M product in a particular application. Given the variety of factors that can affect the use and performance of a 3M product, the user is solely responsible for evaluating the 3M product and determining whether it is fit for a particular purpose and suitable for user's method of application.



**Building and Commercial
Services Division**
St. Paul, MN 55144-1000
1-800-852-9722
www.3M.com/building

3M is a trademark of 3M Company.
Used under license in Canada.
© 3M 2013. All rights reserved.
Asset ID 844095