

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 01 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Certified Mail – Return Receipt Requested

Dear Registrant:

You are receiving this letter because you hold a registration(s) for one or more antimicrobial pesticide products which make claims to provide control of public health microorganisms when applied by fogging and/or misting methods. The EPA seeks to make sure that fogger/mister products are effective as claimed and are labeled in a manner that will prevent unreasonable adverse effects from occurring with regard to human health and the environment. As explained below, the EPA is concerned that fogging/misting products may not be as effective as claimed, and the Agency wants to ensure that these fogging/misting products are accurately labeled. By this letter, we are asking you either to provide existing efficacy data, or to commit to provide new data, which address the public health claims for your fogger/mister products. Alternatively, you may elect to revise the labeling of your affected product(s) and the registrations to delete the public health claims for your fogger/mister product(s). The letter further describes the ways in which you may respond.

EPA recognizes that there is a need for these fogging/misting products under many conditions where sanitization and disinfection is the desired effect. However, the Agency has an ongoing responsibility to ensure that products applied by fogging/misting are efficacious.

This letter is intended to cover only those products that are applied by fogging or misting and that make public health-related claims. When fogging/misting products were originally registered, data generated to support product efficacy were not required to be submitted to the Agency because the claims were not then considered to be public health-related. The Agency now considers the claims made for disinfection and sanitization for products applied by fogging/misting to be public health-related. This would include fogging/misting products that bear

label claims that the product can be used as “an adjunct” to sanitization or disinfection.

The reasons that the EPA believes that fogging/misting methods of application may not be adequately effective include the following:

- Application by fogging/misting results in much smaller particle sizes, different surface coverage characteristics, and potentially reduced efficacy when compared to sanitization or disinfection product applications by spraying, sponging, wiping or mopping.
- The absence of pre-cleaning in the presence of soil contamination, potential reaction with or absorption of the active ingredient for different surfaces, and humidity/temperature fluctuations can also impact distribution and efficacy of the product.
- A surface treated by fogging/misting does not receive the same amount of active ingredient per unit area as the standard methods of application and, as a result, the level of efficacy actually achieved may not be the same level claimed on the label.

The Agency is making the request to submit efficacy data pursuant to 40 CFR Part 161.640, note (b)(1), which states in part:

The Agency has waived all requirements to submit efficacy data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment...However, each registrant must ensure through testing that his products are efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of efficacy data for any pesticide product registered or proposed for registration.

The EPA will examine all efficacy data that registrants have on file and submit for their fogging/misting products. The Agency intends to work closely with registrants to review existing data or to provide guidance on how to generate data to support public health-related claims. EPA will also establish reasonable

timeframes for developing test protocols, reviewing those protocols, and allowing registrants reasonable time to conduct the studies and submit them for EPA review.

The EPA requests that you submit, for each product bearing fogging/misting application instructions, all efficacy test data from your files regarding the use of fogging/misting in achieving the claims listed on the label. If you do not have the efficacy data requested above for your affected product(s), you may, for each affected product, submit a draft efficacy test protocol for EPA's approval prior to generating the required data for each product. Efficacy data generated using the Agency-approved protocol should be submitted to EPA upon completion and data should be sent to the appropriate product manager in the Antimicrobials Division. Alternatively, if you choose not to generate these data, you should submit an amendment deleting any claims for fogging/misting from the registration and label for each affected product and adding the following statement to your registration and label: "This product may be applied only by the methods specified on the labeling."

Further, most of the currently-registered fogging/misting products are registered only for use "as an adjunct" to sanitization or disinfection, while a few products are not registered "as an adjunct" and may be applied directly for sanitization or disinfection. EPA has found there to be confusion over what the terminology "as an adjunct" is intended to mean. Therefore, by this letter, the Agency is also seeking to provide clarity to the label claims that will be allowed for products registered for fogging/misting application. For registrants having products that bear label claims as "an adjunct" to sanitization or disinfection and who wish to retain a fogging or misting application method that will be supported by efficacy data as described above, the term "adjunct" should be deleted from the label.

The EPA requests that you respond with the requested data or the appropriate submission in support of your selected option within 60 days of your receipt of this letter, which has been sent to you by certified return receipt mail.

The EPA is enclosing a list of products identified as having use directions for fogging or misting. If you notice any of your products that are missing, please let us know their product names and EPA Registration Numbers and also select and support an appropriate option for any such product(s).

This letter does not impose binding regulatory requirements. EPA expects to evaluate registrants' submissions and to use the information to identify products which are (or are not) effective sanitizers and disinfectants when applied by fogging or misting. Based on that review, EPA will determine whether further

regulatory actions would be necessary, which might include requiring submission of efficacy data on products for which EPA does not have adequate data and taking regulatory action against products making unsupported claims.

If you have any questions, please contact Dr. Melba Morrow, Antimicrobials Division (morrow.melba@epa.gov; 703-308-2716).

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Bradbury', with a long horizontal line extending to the right.

Steven P. Bradbury, Ph.D.
Director, Office of Pesticide Programs

Enclosure