

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

September 15, 2021

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

TERMINATION OF THE TEMPORARY AMENDMENT TO PESTICIDE REGISTRATION (PR) NOTICE 98-10

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDE PRODUCTS

This Notice applies to products on EPA's List N: Disinfectants for Use Against SARS-CoV-2¹ or products that serve as the source of active ingredient for disinfectants on EPA's List N.

This Notice also applies to food contact surface sanitizer products containing the active ingredient isopropyl alcohol that are used in the essential role of food manufacture and preparation.

Background

On March 30, 2020, EPA issued a time-limited modification (March modification) to Pesticide Registration Notice (PR Notice) 98-10. In response to supply chain disruptions, the March modification allows registrants of currently registered pesticide disinfectant products on EPA's List N: Disinfectants for Use Against SARS-CoV-2 that contain any of the active ingredients specified in the Notice (active ingredients sourced from commodity chemicals²) to use any similar source of the specified active ingredients without having to first apply for and receive EPA approval of an amendment to their pesticide registration identifying the new source of ingredient.

On April 14, 2020, EPA issued a revised time-limited modification (April modification) to PR Notice 98-10 to respond to additional reports of supply chain disruptions by pesticide registrants who manufacture disinfectant products on EPA's List N: Disinfectants for Use Against SARS-CoV-2. Several of the provisions included in the revised time-limited modification to PR Notice 98-10 were also applicable to pesticide products that serve as the source of active ingredient for products on EPA's List N: Disinfectants for Use Against SARS-CoV-2. The purpose of the April modification was to help ensure that disinfectant products remained available as the country responded to the COVID-19 public health emergency.

¹ List N includes products that meet EPA's criteria for use against SARS-CoV-2, the novel coronavirus that causes the disease COVID-19. See: www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

² Previous temporary amendments to PR Notice 98-10 referred to these chemicals as "Commodity Active Ingredients."

On May 11, 2020, EPA issued another time-limited amendment to PR Notice 98-10 (hereinafter referred to as "temporary amendment") to extend some of the supply chain flexibilities in the April modification to products used in the food manufacture and preparation industries. Subsequent to the release of the April modification, the agency received feedback from participants in this sector that they were experiencing challenges acquiring sanitizers used in production facilities processing low moisture products like grains, cereal, flour, and industrial baked goods. To address this need, EPA extended the registration modifications outlined in the April modification to food contact surface sanitizer products containing the active ingredient isopropyl alcohol. Additionally, isopropyl alcohol was added to the list of active ingredients sourced from commodity chemicals.

The Agency has determined that there is no longer a continuing need for these flexibilities and is terminating this amendment. This Notice announces the termination date for the temporary amendment.

Effect of the Temporary Amendment

EPA allowed an alternate notification process for the time period of the temporary amendment. All notifications submitted to EPA under the temporary process are valid only for the time period of the temporary amendment. For the duration of the temporary amendment to PR Notice 98-10 and only for the notifications specified in the temporary amendment (listed below), registrants could sell and distribute products as soon as the notification was received by EPA, without waiting for EPA approval.

- Product chemistry notifications for active ingredients sourced from commodity chemicals.
- Notifications to change sources of active ingredients sourced from commodity chemicals that are not similar.
- Notifications to substitute similar registered sources of active ingredients not sourced from commodity chemicals.
- Notifications to substitute similar inert ingredient sources.
- Notifications to substitute registered sources of active ingredients that are not similar.
- Notification to add an EPA-registered establishment.

<u>Termination of the Temporary Amendment</u>

When issued, EPA stated it would assess the continued need for and scope of the temporary amendment to PR Notice 98-10 on a regular basis and would update it if the EPA determined modifications were necessary. In addition, in recognition of the temporary nature of the amendment, EPA stated it would post a notification at www.epa.gov/pesticides at least seven days prior to terminating the temporary amendment.

In response to updated <u>information from the Centers for Disease Control and Prevention</u> (CDC) that the risk of being infected with COVID-19 by touching contaminated surfaces is considered low, EPA

announced on April 28, 2021 that it is no longer prioritizing Public Health Emergency requests for new products that address surface transmission of SARS-CoV-2. In addition, in light of the nearly 600 EPA-registered products that are on List N, EPA is no longer expediting new product registrations, emerging viral pathogen claims, SARS-CoV-2 claims, and electrostatic spraying directions for products intended to kill SARS-CoV-2 on surfaces.

Consistent with the Agency's April 28, 2021 announcement that it will no longer be expediting approval of List N products for use on surfaces, EPA is terminating the temporary amendment. Registrants have been on notice since the issuance of the temporary amendment that the temporary amendment was time-limited. Since the Fall of 2020, EPA has also been encouraging registrants to amend their registrations by either submitting a notification or amendment, as applicable to make permanent any changes made using the temporary amendments. Further, EPA is not aware that the supply chain issues that justified the issuance of the temporary amendment continue to persist. However, the Agency acknowledges that registrants have made changes in their supply chains based on the temporary amendment, and that registrants require time to make the temporary changes Therefore, EPA is providing 12 months, rather than the seven days guaranteed in the temporary amendment, for registrants to ensure their product (1) is produced using a source of active ingredient identified in the product's approved confidential statement of formula (CSF), or (2) has complied with relevant registration requirements in the absence of the temporary amendment. Permanent changes can be requested either by CSF amendment or notification, as applicable. EPA believes that providing a 12-month notice period is reasonable because it recognizes the reduced need for supply chain flexibilities, while also providing sufficient time for registrants to prepare for the termination of the temporary amendment.

Accordingly, the termination of the temporary amendment will be effective 12 months from today's date, September 15, 2021. After that date, registrants will not be able to release for shipment formulations produced under the conditions of the temporary amendment without first complying with the registration requirements that were in place prior to the issuance of the temporary amendments.

Additional Information

If you have questions about this Notice, please contact John Hebert at 703-308-6249 or by email at: hebert.john@epa.gov.

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