



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 14, 2020

REVISED TEMPORARY AMENDMENT TO
PESTICIDE REGISTRATION (PR) NOTICE 98-10

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

This Notice supersedes and replaces the temporary amendment dated March 30, 2020.

**This Notice only 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.**

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 this Notice (commodity actives) 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.

In follow up to the March modification, EPA is now issuing a revised time-limited 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 this revised time-limited modification to PR Notice 98-10 are 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. EPA intends for this revised temporary amendment to PR Notice 98-10 (hereinafter referred to as "temporary amendment") to help ensure that disinfectant products remain available as the country responds to the current COVID-19 public health emergency. This temporary

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

amendment permits all the registration modifications outlined in the March modification, while also expanding the types of permissible changes to registrations.

Time Period of this Temporary Amendment

The EPA will assess the continued need for and scope of this temporary amendment to PR Notice 98-10 on a regular basis and will update it if the EPA determines modifications are necessary. In order to provide fair and sufficient notice to the public, the EPA will post a notification at www.epa.gov/pesticides at least seven days prior to terminating this temporary amendment.

After that date, registrants will not be able to release for shipment new registered product unless that product is (1) produced using a source of active ingredient identified in the product's approved confidential statement of formula (CSF), or (2) otherwise would have complied with relevant requirements in the absence of this temporary amendment. EPA may consider permanent modifications to PR-Notice 98-10 with respect to registration modifications outlined in the Notice, but any permanent modification will be done following an opportunity for public comment.

EPA's regulations (40 CFR 152.46) state that EPA will provide an opportunity for public comment before it modifies procedures that allow changes to registrations be made by notification. Currently, procedures for notifications are set out in PR Notice 98-10. Because of the critical, immediate need for widespread and continued availability of effective disinfectant products during the current public health emergency, EPA finds good cause to take this action that is in the public interest to allow this time-limited modification to PR-Notice 98-10 without providing an opportunity for public comment under 40 CFR 152.46.²

EPA does not anticipate that the changes allowed through notification by this action will result in any substantive changes to the final pesticide formulations already approved by EPA or that the products' effectiveness will be affected. EPA therefore believes that the products' current precautionary labeling will remain adequately protective and that this action will not cause any unreasonable adverse effects to human health and the environment. These conclusions are based on the presumption that registrants proceed in accordance with the following. **For the purposes of this temporary amendment, the term "similar" means that the active or inert ingredient obtained from the source will have the same CAS number as well as the same purity.**³

EPA is allowing this alternate process for the time period of this temporary amendment. All notifications submitted to EPA under this temporary process will be valid only for the time period of this notice. After the termination date for this temporary amendment, registrants will not be able to release for shipment formulations produced under the conditions discussed below without first submitting a new notification, as appropriate, or an application to amend the confidential statement of formula (CSF) and receiving EPA approval of that amendment.

² Furthermore, this Notice merely alters the notification process used by registrants and does not modify substantive standards. It therefore relates to agency procedure or practice and is not subject to the public procedure requirements of the Administrative Procedure Act. See 5 U.S.C. § 553(b)(A).

³ Any language or formatting differences in this section from the March modification were made for clarity.

For the duration of this temporary amendment to PR Notice 98-10 and only for the notifications discussed below, registrants may sell and distribute products as soon as the notification is received by EPA, without waiting for EPA approval. See the section, Procedure for Submission of Notifications under this Temporary Amendment for more information.

I. Product chemistry notifications for commodity active ingredients.

This section reiterates the changes made in the March modification. Section III.A of PR Notice 98-10 allows for changes to the registered source of active ingredient in a registered product to be submitted by notification when certain criteria are met. However, changes to an unregistered source of active ingredient must be done via amendment. Given the current COVID-19 public health emergency, EPA will temporarily allow registrants of products on List N to use an unregistered source of any of the active ingredient listed below, provided that the new, alternate source is similar to the current source. While it is often important for EPA to examine carefully the particular source of pesticide active ingredients, the value of EPA review and approval is diminished when the pesticide active ingredient is a widely-available and easily-manufactured commodity chemical.

In light of the critical need for available disinfectants during the current COVID-19 public health emergency, EPA is temporarily allowing registrants of pesticide disinfectant products on List N containing the following active ingredients to submit changes by notification in order to use any similar source of the active ingredient to produce their registered disinfectant products:

CAS Number	Chemical Name
64-17-5	Ethanol
7647-01-0	Hydrochloric Acid
7681-52-9	Sodium Hypochlorite
7722-84-1	Hydrogen Peroxide
7790-92-3	Hypochlorous Acid
77-92-9	Citric Acid
79-33-4	L-lactic Acid
79-14-1	Glycolic Acid

Under this provision, EPA is only permitting substitution of sources of specific commodity active ingredients that are similar to the current source, as described in Section III.A. of PR Notice 98-10 (i.e., the purity of resulting product from the alternate source falls within the certified limits of the currently registered formulation for which they are making the source change).⁴

⁴ Chapter 2 of the Registration Manual states that “A product with an unregistered source will not be considered an “identical/substantially similar” product.” For the reasons articulated in this temporary amendment, the Agency believes that the conditions of the source substitutions allowed under this temporary amendment will help to ensure that this action will not cause any unreasonable adverse effects to human health and the environment.

II. Notifications to change sources of commodity active ingredients that are not similar.

In some cases, it may not be possible to substitute commodity sources of active ingredient(s) (see list in Section I) with similar alternate sources in that their purity may vary. In these situations, it will be necessary to adjust the amount of inert ingredients to ensure the nominal concentration of the active ingredient in the product does not change. If the nominal concentration of active ingredient in the product remains the same and adjustment in inert ingredients is limited to water only, self-certification is allowed and confirmatory efficacy data are not required. If your substitution meets the criteria described in this section, you may release the product for sale and distribution once EPA receives your notification in accordance with the procedures below.

III. Notifications to substitute similar registered sources of non-commodity active ingredients.

As stated in PR Notice 98-10, Section III, A. a registrant can submit a notification when substituting similar registered sources of active ingredients. If your substitution meets these criteria, you may release the product for sale and distribution once EPA receives your notification in accordance with the procedures below.

IV. Notifications to substitute similar inert ingredient sources.

As stated in PR Notice 98-10, Section III, B a registrant can submit a notification when substituting a similar inert ingredient source. Concurrent with this submission, composition information from the individual inert supplier must be provided to EPA. If your substitution meets the criteria described in this section, you may release the product for sale and distribution once EPA receives your notification in accordance with the procedures below.

V. Notifications to substitute registered sources of active ingredients that are not similar.

In some cases, it may not be possible to substitute similar registered sources of active ingredient(s), but sources of the same active ingredient may be available with varying purities. In these situations to use the alternate source, it will be necessary to adjust the amount of inert ingredients to ensure the nominal concentration of the active ingredient in the resulting product does not change. If the nominal concentration of active ingredient in the product remains the same and adjustment in inert ingredients is limited to water only, this change will be allowed by notification and confirmatory efficacy data are not required. If your substitution meets the criteria described in this section, you may release the product for sale and distribution once EPA receives your notification in accordance with the procedures below.

VI. Notification to add an EPA-registered establishment.

For registrants seeking to add the EPA-registered establishments for formulations that have a registered source of active ingredient, and where there are no other changes to the formulation other than those described in this temporary amendment, the change may be made by notification. If your notification meets the criteria described in this section, you may release the product for sale and distribution once EPA receives your notification in accordance with the procedures below. The new facility must be an EPA-registered establishment.

Procedure for Submission of Notifications under this Temporary Amendment

The following is the procedure for registrants to submit notifications under this temporary amendment. As stated above, this notification process is only for currently registered disinfectant products approved for use against SARS-CoV-2, as well as products that serve as the source of active ingredient for those products, as set forth below. Each notification as described in Sections II through V must include a copy of the revised confidential statement(s) of formula (EPA Form 8570-4) and the following information in your cover letter to EPA:

a subject line that clearly indicates that this is a ‘notification per TEMPORARY AMENDMENT TO PR NOTICE 98-10 (April 14, 2020) for EPA Registration No. XXXXXX and [insert product name]”;

- the active ingredient; and
- the following certification statement⁵:

"[Name of Registrant] is submitting this notification consistent with the provisions of PR Notice 98-10 and [insert section(s)] of the Temporary Amendment to PR Notice 98-10 dated April 14, 2020, and no other changes have been made to the confidential statement of formula or labeling of this product. I confirm that the ingredients statement of this label remains truthful. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this self-certification is not consistent with the terms of PR Notice 98-10, the Temporary Amendment 98-10 dated April 14, 2020, and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under sections 12 and 14 of FIFRA. "

Submit your application via the CDX portal (<https://cdx.epa.gov/>). Once received, please email the CDX tracking number (CDX 2020_XXXXXXX) to the Product Manager for your product.

A registrant may distribute or sell a product modified according to this temporary amendment to PR Notice 98-10 once EPA receives the notification. For purposes of this Notice, receipt occurs when the requestor receives a CDX number when submitting the application via the CDX portal (<https://cdx.epa.gov/>).

⁵ The certification statement has been updated from the March modification.

Potential Future Changes to this Temporary Amendment to PR Notice 98-10

As the country continues to respond to the COVID-19 public health emergency, it is possible that additional changes to this temporary amendment may be necessary. Accordingly, the Agency reserves the right to further revise this temporary amendment without providing an opportunity for public comment.

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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