



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

March 30, 2020

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

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

EPA is issuing a time-limited modification to Pesticide Registration Notice (PR Notice) 98-10 to allow registrants of currently registered pesticide disinfectant products containing any of the active ingredients specified in this notice to use any source of the specified active ingredients without having to first apply for and receive EPA approval of an amendment to their pesticide registration to identify the new source of ingredient. In response to reports of supply chain disruptions by pesticide registrants who manufacture disinfectant products on EPA's List N: Disinfectants for Use Against SARS-CoV-2¹, EPA is issuing this temporary amendment to PR Notice 98-10 to help ensure that disinfectant products remain available as the country responds to the current pandemic.

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 an easily-manufactured commodity chemical. In light of the critical need for available disinfectants during the current COVID-19 pandemic, EPA is temporarily allowing registrants of pesticide disinfectant products on List N containing the following active ingredients to use any 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

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

7722-84-1	Hydrogen Peroxide
7790-92-3	Hypochlorous Acid
77-92-9	Citric Acid
79-33-4	L-lactic acid

EPA regulations (40 CFR §152.46) generally provide that EPA will not allow changes to registrations be made by notification, such as allowed by PR-Notice 98-10, without first providing an opportunity for public comment. Because of the critical, immediate need for widespread and continued availability of effective disinfectant products during the current pandemic, EPA finds that it is in the public interest to allow this time-limited modification to PR-Notice 98-10 without providing an opportunity for public comment. This action only allows substitution of sources of specific commodity active ingredients which are chemically 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).² Because this action will only allow products to be sold that are essentially identical in composition to already-registered products, this action will not cause any unreasonable adverse effects to human health and the environment.

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 produced using a source of active ingredient identified in the product's approved confidential statement of formula (CSF) or otherwise would have complied with relevant requirements in the absence of this temporary amendment. EPA may consider a permanent modification to PR-Notice 98-10 with respect to the use of commodity chemicals as sources of active ingredients in pesticide products, but any permanent modification would be done following an opportunity for public comment.

Product Chemistry Notifications under this Temporary Amendment to PR Notice 98-10

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 pandemic, EPA will temporarily allow registrants of products on List N to

² 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.

use an unregistered source of any of the active ingredient listed below, provided that the resulting formulation is chemically similar to the current source (i.e., meets the criteria given in Section III.A. of PR Notice 98-10):

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

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, registrants will not be able to release for shipment formulations using similar registered active ingredients unless the registered product is produced using a source of active ingredient identified in the product's accepted CSF). To use an alternate unregistered source beyond the time period of this notice, the registrant must submit an application to amend the CSF.

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 set forth below. Each notification must include 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 (*Insert date or other citation*) for EPA Registration No. XXXXXX and [insert product name]";
- the active ingredient; and
- a statement that:

"[Name of Registrant] is notifying EPA of its intent to use one or more alternate, unregistered sources of active ingredient listed in the TEMPORARY AMENDMENT TO PESTICIDE REGISTRATION (PR) NOTICE 98-10 (*Insert date or other citation*) in the formulation of EPA Registration No. [xxx-xx, etc.]. Each source is chemically identical to (*i.e.*, within the certified limits of) the active ingredients in the Confidential Statements of Formula previously accepted by EPA [insert CSF date(s)]. This self-certification is consistent with the provisions of PR Notice 98-10 and no other changes have been made to the confidential statement of formula or labeling of this product. Further, 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 and 40

CFR 152. 46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under section 12 and 14 of FIFRA. "

Submit your application via the [CDX portal \(https://cdx.epa.gov/\)](https://cdx.epa.gov/). Once you submit or if you have already submitted your application, please email disinfectantslist@epa.gov with your CDX tracking number (CDX_2020_XXXXXXX).

A registrant may distribute or sell a product modified according to this temporary amendment to PR Notice 98-10 once EPA receives the notification.

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

As the country continues to respond to the COVID-19 pandemic, it is possible that additional changes to this temporary amendment may be necessary. The Agency reserves the right to make revisions to 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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