EPA Announces Additional Action to Assure Availability of Disinfectant Products for Use Against the Novel Coronavirus

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On March 31, 2020, the U.S. Environmental Protection Agency (EPA) announced it is taking further action to help ease the production and availability of EPA-registered disinfectants by temporarily allowing manufacturers of certain already-registered EPA disinfectant products to obtain certain active ingredients from any source without prior approval from EPA. This only applies to products on EPA's List N: Disinfectants for Use Against SARS-CoV-2 (List N). EPA announced on March 26, 2020, similar action on certain inert ingredients.

EPA typically requires disinfectant manufacturers to first apply for and receive EPA approval prior to making a change in the source of the active ingredient. Under this temporary amendment, however, manufacturers can source certain active ingredients from alternate suppliers by informing EPA. Once EPA has been notified, the registrant can immediately distribute or sell a product modified according to this temporary amendment, provided that the resulting formulation is chemically similar to the current formulation (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). EPA states that by allowing manufacturers to obtain certain active ingredients from any source it will help alleviate reports of supply chain disruptions by pesticide registrants who manufacture disinfectant products on List N.

The eligible active ingredients are:

- Citric Acid, Chemical Abstracts Service Registry Number (CASRN) 77-92-9;
- Ethanol, CASRN 64-17-5;
- Glycolic Acid, CASRN 79-14-1;
- Hydrochloric Acid, CASRN 7647-01-0;
- Hypochlorous Acid, CASRN 7790-92-3;
- Hydrogen Peroxide, CASRN 7722-84-1;
- L-Lactic Acid, CASRN 79-33-4; and
- Sodium Hypochlorite, CASRN 7681-52-9.

EPA will assess the continued need for and scope of this temporary amendment on a regular basis and will update it if EPA determines modifications are necessary. EPA will notify the public at least seven days prior to terminating this temporary amendment at <u>www.epa.gov/pesticides</u>.

After the termination date of the temporary amendment, 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 states in its <u>temporary amendment to Pesticide Registration (PR) Notice 98-10</u>, the following procedures to submit a notification for currently registered disinfectant products listed on EPA's List N:

- A cover letter with 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
- The following statement:

[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]. 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. Section 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 C.F.R. 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.

Applications must be submitted via the <u>CDX portal</u>. At this time, EPA is not accepting paper applications. Once an application is submitted, EPA requests that an email is sent to <u>disinfectantslist@epa.gov</u> with the 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.

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National Law Review, Volume X, Number 91

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