

EPA Takes Action to Ease the Production of Disinfectants Approved for Use Against the Novel Coronavirus



Citing reports of supply chain disruptions by manufacturers of registered disinfectant products approved for use against the novel coronavirus, the U.S. Environmental Protection Agency (“EPA”) [announced on March 31, 2020](#) that it will temporarily allow manufacturers of such products to obtain certain “commodity” active ingredients from different suppliers without first obtaining a registration amendment. This action follows the Agency’s recent announcement that pesticide manufacturers may similarly obtain certain [“commodity inert ingredients”](#) from different suppliers without first notifying EPA.

According to EPA, this change is intended to help pesticide manufacturers quickly source and obtain the active ingredients necessary to produce disinfectant products approved by the Agency on its [List N: Disinfectants for Use Against SARS-CoV-2](#).

A. Background

An active ingredient is a chemical in a pesticide product that acts to prevent, destroy, repel, or mitigate a pest, or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer. Consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) and Pesticide Registration Notice 98-10, EPA permits pesticide manufacturers to change the source of an active ingredient to an alternate, registered source by notification if the alternate source is both (1) registered for at least the same uses for which the formulated product is registered and (2) chemically similar to the current source. However, EPA generally requires that manufacturers apply for and obtain EPA approval before changing to an unregistered source of any active ingredient.

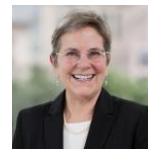
April 1, 2020

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B. Allowing Use of Some Unregistered Active Ingredient Sources by Notification Alone

With this latest action, however, EPA will temporarily permit manufacturers of listed anti-coronavirus disinfectants to source certain active ingredients from unregistered sources by notification alone, and without first obtaining Agency approval. Only registered disinfectant products included on List N are affected by this change, and only with regard to the following “widely available” and “easily-manufactured commodity” active ingredients:

- Citric Acid
- Ethanol
- Glycolic Acid
- Hydrochloric Acid
- Hypochlorous Acid
- Hydrogen Peroxide
- L-Lactic Acid
- Sodium Hypochlorite

Notifications submitted to EPA under this temporary process will be valid only as long as it remains in effect. EPA will regularly assess the need for and scope of this new allowance, and will provide at least seven days’ notice prior to its termination. After that date, pesticide registrants will not be permitted to release for shipment any new registered product unless it is produced with ingredients as approved or permitted in the absence of the temporary amendment. EPA also expressly notes that additional changes to its registration policies may be forthcoming as U.S. efforts to respond to the COVID-19 pandemic continue.

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