

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

#### **COMPLIANCE ADVISORY**

January 2021 (Replaces May 2020 Compliance Advisory)

# What You Need to Know Regarding Products Making Claims to Kill the *Coronavirus*<sup>1</sup> Causing COVID-19 (UPDATE)

The purpose of this Compliance Advisory is to address concerns related to products being used to disinfect surfaces which include claims to be effective against SARS-CoV-2, the *coronavirus* causing the disease COVID-19. For some of these products, those claims have not been reviewed or accepted by EPA and, therefore, may present a risk to consumers, and healthcare providers in particular.

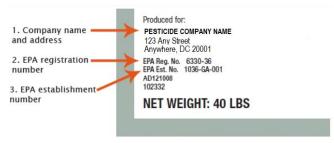
# Products claiming to be effective against the coronavirus causing COVID-19

Consumers use disinfectants to kill, control, or otherwise be effective against a wide range of pests, including microorganisms like viruses. Products that claim to kill or be otherwise effective against pests, including viruses, are pesticides and must be registered with the U.S. Environmental Protection Agency (EPA or the agency) prior to distribution or sale. Generally, these products may not be sold or distributed *unless* they have been properly tested and are registered by the EPA. There are additional state registration requirements as well.

The agency will not register a product claiming to be effective against *coronavirus* until it has determined that the product will not pose an unreasonable risk and it will be effective when used according to the label directions. EPA maintains "List N," which is a list of disinfectants that meet EPA's criteria for use against the virus that causes COVID-19. While many of the surface disinfectant products on List N have not been tested specifically against *coronavirus*, EPA expects them to be effective because they demonstrate efficacy against a harder-to-kill virus or another human coronavirus similar to the one causing COVID-19. Given that the *coronavirus* causing COVID-19 is now available for laboratory testing, products with demonstrated effectiveness against that specific virus, in addition to products with demonstrated effectiveness against harder to kill viruses, may be approved for List N.

<sup>&</sup>lt;sup>1</sup> There are many types of coronaviruses and this advisory addresses the specific virus called SARS-CoV-2 that causes the disease COVID-19. Thus, the use of the word "*coronavirus*" in this Advisory refers to SARS-CoV-2.

To find a product on the EPA List N, consumers should check the EPA registration number on the product to ensure it is on the list. Please note that just because a product label states that it "kills 99.9% of viruses," this does not necessarily mean that it will be effective against the coronavirus. Follow all



label directions including the recommended contact time, which is the amount of time the product needs to remain wet on a surface.

# What is the difference between an EPA registration number and an EPA establishment number?

An EPA establishment number is not the same as an EPA registration number. An EPA registration number signifies that the pesticide and its claims have been reviewed and approved by EPA. An establishment number identifies the EPA-registered location where the product was produced. EPA provides a National List of Active EPA-Registered Foreign and Domestic Pesticide and/or Device-Producing Establishments at: <a href="https://www.epa.gov/compliance/national-list-active-epa-registered-foreign-and-domestic-pesticide-andor-device-producing">https://www.epa.gov/compliance/national-list-active-epa-registered-foreign-and-domestic-pesticide-andor-device-producing</a>.

#### Devices that claim to kill the coronavirus

In contrast to a chemical pesticide, a pesticidal device is an instrument or other machine that is used to destroy, repel, trap, or mitigate any pests, including viruses. A device must work solely by physical means (such as electricity, light or mechanics). If the device incorporates a substance or mixture of substances to perform its intended pesticidal purpose, then it is considered a pesticide product, not a device. Examples of devices may include ozone generators, UV lights, etc. Unlike chemical pesticides, EPA does not register devices and, therefore, does not routinely review their safety or efficacy. Because EPA does not review or register pesticidal devices, EPA cannot confirm whether, or under what circumstances, devices might be effective against the spread of *coronavirus*. Hence, these products are not included on List N.

Although pesticidal devices are not required to be registered with EPA, there are legal requirements that apply. For example, device labels must include adequate warning and caution statements and directions for use as well as the EPA *establishment number* (they will not have an EPA *registration number* because they are not subject to the same registration requirements as pesticides). Additionally, making false or misleading labeling claims about the safety or efficacy of a pesticidal device is prohibited and could result in the issuance of a Stop Sale, Use, or Removal Order and penalties under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). For more information on devices, see: <a href="https://www.epa.gov/safepestcontrol/pesticide-devices-guide-consumers">https://www.epa.gov/safepestcontrol/pesticide-devices-guide-consumers</a>.

### **Human Health Concerns**

Products that are not EPA-registered but claim to kill and/or be effective against *coronavirus*, may not actually be effective against the spread of this pathogen. In addition, because EPA has not conducted a human health risk assessment to determine the safety of these products, the extent to which using these unregistered products may result in adverse effects that are harmful

to human health is uncertain. As for pesticide products that are registered with the EPA, using them in a manner inconsistent with their labeling may diminish their efficacy, cause adverse effects to human health, or both.

## **Compliance Concerns**

In the United States, it is unlawful to distribute or sell a pesticide which includes claims that it will kill a particular pathogen, *unless* that pesticide is registered by EPA and that particular claim has been deemed acceptable by the agency. In some instances, companies have unlawfully added additional claims to the labels of their registered pesticide products that have not been approved by EPA. For example, a claim for persisting or long-lasting effect against viruses, referred to as "residual claims" (i.e., claims that a product provides an ongoing antimicrobial effect beyond the initial time of application, ranging from days to weeks to months), may be accepted by EPA only when supported by acceptable studies demonstrating satisfactory residual efficacy. Until EPA approves a residual claim, it cannot lawfully be included on a registered product as part of distribution or sale. For more information on residual claims, see:

https://www.epa.gov/coronavirus/there-anything-i-can-do-make-surfaces-resistant-sars-cov-2. For more information on registering products with residual claims, see EPA's Interim Guidance: https://www.epa.gov/pesticide-registration/interim-guidance-expedited-review-products-adding-residual-efficacy-claims

EPA is receiving a steady stream of tips/complaints concerning potentially false or misleading claims, including efficacy claims, associated with pesticides and devices. These tips and complaints are being actively reviewed and efforts are being made to identify violative products. EPA intends to pursue enforcement against products making false and misleading claims regarding their efficacy against the *coronavirus*. EPA is particularly concerned with pesticide and pesticide device products sold online on e-commerce platforms that are fraudulent, counterfeit, and/or otherwise ineffective. EPA is also coordinating with the U.S. Department of Justice, U.S. Customs and Border Protection, and other federal partners to bring the full force of the law against those selling or otherwise distributing violative products.

# For more information on disinfectants, including Frequently Asked Questions and up-todate press releases:

https://www.epa.gov/coronavirus

#### For more information on EPA's enforcement actions:

https://www.epa.gov/enforcement/covid-19-enforcement-and-compliance-resources

## For tips and complaints related to products making coronavirus claims:

https://echo.epa.gov/report-environmental-violations

#### **DISCLAIMER**

Nothing in this Compliance Advisory is meant to replace or revise any EPA regulatory provisions of any other part of the Code of Federal Regulations, the Federal Register, or FIFRA.