



OPP's COVID-19 Response Actions

Pesticide Program Dialogue Committee

May 2020

Office of Pesticide Programs



Discussion Topics

- Emerging Viral Pathogens Policy
- Creation of List N
- Addressing Potential Supply Chain Disruptions
- Human Coronavirus Efficacy Testing Program



Emerging Viral Pathogens (EVP) Guidance

January 29, 2020: EPA implemented guidance called the Emerging Viral Pathogen guidance that was developed exactly for the situation we are facing today.

- The EVP guidance:
 - sets up a two-step process to enable the use of EPA-registered disinfectant products against emerging viral pathogens not identified on the product label
 - provides a pathway for registrants to make off-label claims for new emerging micro-organisms (like SARS-CoV-2) because they have data showing their products are effective against harder to kill viruses.



Emerging Viral Pathogens Guidance: How It Works

- First stage: Registrants with an eligible disinfectant product may request to add a claim to add an emerging viral pathogen designated statement to the master label and additional terms to the product registration
- Second stage: Once the guidance is triggered in response to a human or animal disease outbreak caused by an emerging virus, registrants of products with the previously approved EVP claims may make off-label communications that the product may be used against the specific emerging virus



Emerging Viral Pathogens Guidance: Eligibility Criteria

- The product is an EPA-registered, hospital/healthcare or broad-spectrum disinfectant with directions for use on hard, porous or non-porous surfaces AND
- The currently accepted product label for an EPA registered product should have disinfectant efficacy claims against at least one of the following viral pathogen groupings:
- **A product should be approved by EPA to inactivate at least:**
 - One large or one small non-enveloped virus **to be eligible for use against an enveloped emerging viral pathogen (e.g., SARS-CoV-2)**
 - One small, non-enveloped virus **to be eligible for use against a large, non-enveloped emerging viral pathogen**
 - Two small, non-enveloped viruses with each from a different viral family **to be eligible for use against a small, non-enveloped emerging viral pathogen**



Creation of List N

- Disinfectants for Use Against SARS-CoV-2
- Currently over 400 products on the list
- Updated on a weekly basis
- Includes Frequently Asked Questions
- Includes Submission Information for Registrants

EPA List N Search Tool

List N Tool: COVID-19 Disinfectants

Feedback

EPA Registration Number

Active Ingredient

Use Site

Contact Time

Browse All

Keyword Search

Enter only the first two parts of the registration number (ex. 1234-12)

Show results Clear results

<https://cfpub.epa.gov/giwiz/disinfectants/index.cfm>



Addressing Potential Supply Chain Disruptions

- Time-limited modifications to the registration procedures to allow registrants to make certain changes to their formulations more swiftly
- Primary focus is for products on List N
- May 2020 amendment expands scope to include food contact surface sanitizer products containing the active ingredient isopropyl alcohol that are used in the essential role of food manufacture and preparation



Addressing Potential Supply Chain Disruptions

- Changes permitted:
 - Substitution of sources of active ingredients
 - Substitution of sources of inert ingredients
 - Addition of EPA-registered establishments
- EPA does not anticipate that these types of changes will result in substantive changes to the final product formulations
- EPA may decide to make these procedures permanent, but will only do so following an opportunity for public comment



Human Coronavirus Efficacy Testing Program

- To be conducted by OPP's Microbiology Laboratory at the Environmental Science Center (ESC), Ft. Meade, MD
- 20-year history of developing test methods for infectious pathogens, including:
 - Clostridium difficile
 - Candida auris
 - Legionella
 - Other organisms for which disinfection in clinical settings is of key importance

The OPP laboratory will be studying the relationship between human coronaviruses (biosafety level 2) and SARS CoV2 (biosafety level 3) to determine their comparative tolerance to disinfectants



Human Coronavirus Efficacy Testing Program

- Labs are just starting to test against the SARS-CoV-2;
- The method will be evaluated for testing products against human coronavirus on porous surfaces
- EPA will issue regulatory guidance if the test method for soft, porous materials is verified and standardized
- First PRIA submissions to EPA arrived in mid-May



Other Requests for Flexibility Being Considered

- Providing increased communications for consumers at the point of sale
- Addressing shortages of personal protective equipment
- Additional options for providing annual worker protection training
- Expanded flexibilities for continuing applicator certification programs



COVID-19 Resources

- For information about EPA's response to COVID-19 see: <https://www.epa.gov/coronavirus>
- For a list of products qualified for use against SARS-CoV-2, the virus that causes COVID-19 see: [List N](#) (mobile friendly)
 - Searching by a product's registration number is the best way to ensure that it is approved for use against SARS-CoV-2
- Q&A section of EPA's COVID-19 website: <https://www.epa.gov/coronavirus/frequent-questions-about-disinfectants-and-coronavirus-covid-19>



Additional COVID-19 Resources

Topic	Contact
General registration questions, including how to register an antimicrobial product	OPP_AD_Ombudsman@epa.gov
Questions about adding a product to List N	disinfectantslist@epa.gov
Antimicrobial products efficacy questions	AD_Efficacy@epa.gov
Citizen inquiries	pesticidequestions@epa.gov
Label information for registered pesticide products	EPA's Pesticide Product Label System
All other questions	EPA Hotlines