OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

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Interim Guidance for the Evaluation of Products for Claims Against Viruses

I. Background and Purpose

EPA regulations require that claims on antimicrobial pesticide products be supported by testing demonstrating that the product is "efficacious when used in accordance with label directions and commonly accepted pest control practices." 40 C.F.R. § 158.2220(a)(1). The product performance testing required for antimicrobial pesticide products varies based on the nature of the claims made on such products, including claims regarding the level of efficacy and pests against which the products are efficacious. For antimicrobial pesticide products bearing a public health claim—defined in 40 C.F.R. § 158.2204(a) as "a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment"— EPA's data requirement regulations outline the specific performance data that applicants are expected to submit in support of the registration of such products.[1] 40 C.F.R. § 158.2220(c). These data requirement regulations outline three tiers of antimicrobial pesticide products and define differing data requirements for public health antimicrobial pesticide products based on the claims that are registered on a product: sterilant, disinfectant, sanitizer. *Id.* (see also definitions below in section II).

Historically, EPA has approved claims for efficacy against viruses only as additional claims on certain antimicrobial products, such as those with sterilant and disinfectant claims, but not those that bear only sanitizer claims. This approach was based on how EPA's antimicrobial data requirement regulations define the tiers of antimicrobial pesticide products, and the Agency's historical understanding of the diverse use patterns of each tier of products. Specifically, the definition of a

[1] The registration of antimicrobial pesticide products that do not bear public health claims must also be supported by efficacy testing that demonstrates that the product is "efficacious when used in accordance with label directions and commonly accepted practices," and EPA reserves the right to require submission of such data on a case-by-case basis. 40 C.F.R. § 158.2220(a)(3).

"sanitizer" in 40 CFR 158.2203 is silent on the effectiveness of sanitizers against viruses, while the definitions for "disinfectant" and "sterilant" both include efficacy against viruses. Additionally, previous EPA policy has considered that viruses are primarily a concern in hospitals and other healthcare sites where disinfectants may be used and recommended as a component of infection prevention practices. However, as a result of the COVID-19 Pandemic, EPA recognizes the public health implications of this policy and has reconsidered the addition of specific virus claims on sanitizer product labels.

The purpose of this guidance is to expand the availability of virucidal claims for antimicrobial pesticides and provide a framework for registrants who seek to make such claims. This guidance reiterates recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for hard surface disinfection claims consistent with the 810.2200 test guidelines and provides recommended test methods and regulatory guidance for the addition of virucidal claims to products that meet the criteria for food/non-food contact sanitizer claims consistent with the 810.2300 test guidelines. This guidance only covers the addition of a virucidal claim to a product that has met the criteria for a bactericidal disinfectant and/or sanitizer.[2] In addition, this guidance is not intended to cover residual (long-lasting) sanitizer claims. If residual claims are to be added to the product label, consult with the Agency and/or visit https://www.epa.gov/pesticide-registration/guidance-products-adding-residual-efficacy-claims.

The methods and performance standards applicable to this expanded availability of virucidal claims are summarized in Table 1. Of note, these virucidal claims will utilize the same test methods and performance standards used to support existing virucidal claims, without expecting a reduction in product performance against viruses under the expanded policy.

This guidance is intended to allow registrants to provide consumers with additional products that are effective against viruses including SARS-CoV-2. Additional anticipated benefits include the availability of more products with reduced contact times (time the surface must remain wet) and/or more products on EPA's Design for the Environment (DFE) list that are also effective against viruses.

This guidance is not binding on EPA or any outside parties, and EPA may depart from said guidance where circumstances warrant and without prior notice. Registrants and applicants may propose and submit alternative practices (e.g., modifications to the recommended test methodology) to the Agency for assessment. The Agency will evaluate any proposed modifications for appropriateness on a case-by-case basis. This guidance may be updated in the future.

II. Definitions:

- **Sterilant** – A substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses. 40 C.F.R. § 158.2203.
    i. Products with sterilant claims are commonly used in laboratories, pharmaceutical clean rooms, and similar environments where sterilization is necessary.
- **Disinfectant** – A substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment. 40 C.F.R. § 158.2203.

[2] This guidance does not provide any additional information for adding virucidal claims to sterilant products. If you wish to add specific virucidal claims to sterilants, consult with the Agency.

EPA categorizes products bearing disinfectant claims that it registers into three categories based on the type of efficacy data submitted: Limited, General (or Broad-spectrum), and Hospital.

i. Limited – an effective disinfectant against *only* a specific major group of bacteria, either gram-positive or gram-negative of one gram-type, with efficacy data against *Staphylococcus aureus* (gram-positive) or *Salmonella enterica* (gram-negative).

ii. Broad-Spectrum (General) – an effective disinfectant against both gram-positive and gram-negative bacteria with efficacy data against *Staphylococcus aureus* and *Salmonella enterica* (or *Pseudomonas aeruginosa*). Products in this category are registered for use in a variety of non-healthcare use-sites: residential, commercial, institutional, and others.

iii. Hospital – an effective disinfectant against both gram-positive and gram-negative bacteria, with efficacy data against *Staphylococcus aureus* and the nosocomial bacterial pathogen *Pseudomonas aeruginosa*. These disinfectants are generally registered for use in hospitals, clinics, dental offices, or other healthcare related facilities.

- **Sanitizer** – a substance, or mixture of substances, which reduces the bacteria population in the inanimate environment by significant numbers but does not destroy or eliminate all bacteria. 40 C.F.R. § 158.2203.

    i. Products bearing sanitizer claims can be registered for use on food or non-food contact surfaces.

III. Product Eligibility and Test Criteria

Product eligibility for the addition of a hard surface virucidal claim to a public health antimicrobial pesticide product pursuant to this guidance is based on the current 810.2200 test guideline. This guidance proposes no change to the test methods or performance standards recommended for a product to meet any of the antimicrobial pesticide product definitions or fall under the categories of claims on such products (see section II).

The expansion of the availability of virucidal claims under this guidance will facilitate the addition of virus claims to products bearing only sanitizer claims. Products should meet the test guidance requirements as described in 810.2300 – Test Guidelines for Sanitizer products (food or non-food contact sanitization) before a virucidal claim is added. Since there will be no changes to the test methods or performance standards recommended for virus claims, there is no concern about a reduced level of efficacy against viruses.

Products that meet the basic criteria to allow for sanitizer claims, as outlined in the current 810.2300 test guideline, and have data to support the addition of virucidal label claims, may be used in non-healthcare use-sites in residential, commercial and institutional settings (e.g., cafeterias). Furthermore, addition of a virucidal claim to a product bearing only sanitizer claims does not imply that the product can be used in healthcare settings, due to the higher level of efficacy against bacteria that is expected in hospital patient care areas. As a result, it may be appropriate to consider labeling these products to indicate “Not for use in patient care areas of hospital/healthcare facilities.”

For a summary of the Efficacy Test Guidelines - General considerations utilize: **"***EPA's Product Performance Test Guidelines; OCSPP 810.2000: General Considerations for Testing Public Health Antimicrobial Pesticides*".

To support a claim as a sanitizer utilize ***"EPA's Product Performance Test Guidelines; OCSPP 810.2300: Sanitizers for Use on Hard Surfaces—Efficacy Data Recommendations"*.**

To add a virucidal claim to either a disinfectant or a sanitizer, utilize ***"EPA's Product Performance Test Guidelines; OCSPP 810.2200: Disinfectants for Use on Environmental Surfaces Guidance for Efficacy Testing"*** section G "Virucidal Claims" to develop virucidal data.

- As specified in 810.2200, two batches (lots) of product at the Lower Certified Limit (LCL) should be tested for the hardest to kill virus strain on the product label. For all additional viruses, two batches of product at the nominal concentration should be tested. Testing can be conducted on virus surrogates and non-surrogates as specified in the 810.2200 guidance. For non-surrogate viruses, one surface carrier per batch should be tested and for surrogates, two surface carriers per batch.
    i. Surrogates are alternative microbes or strains of microbes used to represent a pathogenic public health organism typically used due to biosafety concerns, ease of culturing, and/or availability.
- The maximum contact time to achieve the performance standard for viruses should be consistent with the maximum contact time for the bactericidal claim (see Table 1).
- Efficacy testing against SARS-CoV-2 should be tested using 3 lots for the first strain on the label.

To view frequently asked questions regarding the Series 810 guidelines, utilize "https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/frequent-questions-2018-series-810-product".

Table 1. Product Eligibility and Test Criteria

Claim	Sub-category	Organism	Method*	Performance standard	Contact time
Disinfectant	Hospital	*S. aureus* (ATCC 6538) & *P. aeruginosa* (ATCC 15442)	AOAC UDM, SOP MB-05, GST or modified GST depending on product form and use (liquid; spray; towelette)	Complete kill on number of carriers prescribed in 810.2200- *varies by organism and method*	≤ 10 minutes
	Broad Spectrum	*S. aureus* (ATCC 6538) & *S. enterica* (ATCC 10708) or *P. aeruginosa* (ATCC 15442)			

Sanitizer	Non-food contact Hard surface	*S. aureus* (ATCC 6538) & *K. pneumoniae* (ATCC 4352) *or* *E. aerogenes* (ATCC 13048)	ASTM E1153	≥ 99.9% (3-log)	≤ 5 minutes
	Food-contact Hard surface – Halide actives	*S. enterica* (ATCC 10708) or *S. aureus* (ATCC 6538)	AOAC International Chlorine (Available) in Disinfectants Germicidal Equivalent Concentration	Test results should demonstrate product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine.	Not Applicable for test method. Label states 1 minute
	Food-contact Hard surface – Non-halide actives	*E. coli* (ATCC 11229) and *S. aureus* (ATCC 6538)	AOAC International Germicidal and Detergent Sanitizing Action of Disinfectants	≥ 99.999% (5-log)	≤ 30 seconds (label states 1 minute)
NEW: **Virucidal**	**NEW:** Virucidal claims may be added to products with the above disinfectant or sanitizer claims	**Virus claimed on the label or approved surrogate**	**ASTM E1053 (modified for formulation type)**	**≥ 99.9% (3-log)**	≤ 10 minutes for disinfectants ≤ 5 minutes for non-food contact sanitizers ≤ 30 seconds for food contact sanitizers (label states 1 minute)

*AOAC = AOAC International (formerly Association of Official Analytical Chemists) / ASTM = ASTM International (formerly American Society for Testing and Materials)

IV. Regulatory Submission Process and Implementation

- Registration Process:

  i. Applicants seeking product registration(s) or registration amendment(s) under this new policy should follow the regulatory and submission process for registration for antimicrobial products. The regulatory and submission process can be found here: Pesticide Registration Manual (https://www.epa.gov/pesticide-registration/pesticide-registration-manual)

  ii. Applicants seeking product registrations, submitting no new data, should follow the process for the non-coded PRIA fast track amendments. Applicants seeking product registrations, submitting new data, should follow the process for amendments requiring product-specific data. See the following for details: Pesticide Registration Manual: Chapter 6 - Amending a Registered Pesticide Product (https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-6-amending-registered-pesticide#fasttrack).

  iii. When submitting a new product registration and/or a label amendment, provide an accompanying cover letter including the intent to submit under this time limited guidance, along with the product-specific Terms of Registration (See Attachment 1).

- Implementation:

  i. Expansion of the availability of virucidal claims represents a significant policy shift. As such, EPA intends to grant the addition of virucidal claims associated with sanitizer claims for a time-limited period of a maximum of ten years, starting from the date the guidance is finalized for use. Registrants interested in registering sanitizer products with virucidal claims or adding virucidal claims to previously registered sanitizer products should do so within the ten-year period. The time-limited period will expire on October 10, 2034.

  ii. Public comments provided through www.regulations.gov under docket ID: EPA-HQ-OPP-2023-0288 on or before October 10, 2032, will be considered to determine if a revision to the guidance is necessary or if the guidance can be re-issued without a time limitation. Prior to the end of the ten-year period, the Agency will review the record and may make suggestions for changes to the policy, as necessary, or decide to make the policy permanent. The time-limited registration applies to all products seeking to obtain such registration and it is not an individualized time period.

     a. For example, if a registrant were to submit an application to add a new virucidal claim to a sanitizer-only product on September 1, 2029, that product claim would be valid until October 10, 2034.

  iii. Products registered under this time limited registration will receive a registration with terms and conditions. These time-limited registrations will be tracked internally to capture all products under this registration and provide a way for communication with the registrants, as necessary.

  iv. The purpose of the 10-year time-limited registration timeframe is to allow registrants to come forth and use the guidance for registration and for the Agency

to evaluate the benefits, concerns and related experience to inform a decision on the permanence of this interim guidance.

V. Label Guidance:

Note: The following language is intended to provide general examples of potential label language pertaining to new virucidal claims on products that have only sanitizer claims. The Agency will review all labels in the full context of all use directions and supporting efficacy data.

- Define Use Directions appropriately and separate according to the relevant test microbes, efficacy claims, and contact times to avoid end user confusion.
  i. It is recommended to organize claims using headings and sub-headings to better organize the label claims.
- For products that **only** have sanitizer claims seeking a virucidal claim, language should be present on the label to indicate the product should not be used in patient care areas of healthcare settings, for example – "Not for use in patient care areas of hospital/healthcare facilities".
  i. Patient care areas include all areas of a hospital or healthcare setting where direct patient care is delivered and where patient diagnostic or treatment procedures are performed (i.e., operating rooms, nursing homes, dialysis centers, birthing rooms, cancer treatment facilities, emergency rooms, waiting rooms).
  ii. Examples of non-patient care areas include, hospital cafeterias, staff break rooms, receptionist desks, billing and coding spaces.
  iii. To emphasize proper use of the products, claim language such as, "Not for use as a disinfectant" may be added to the label to help differentiate product performance for the end user.
- The following claim language may be added to the label to emphasize where the product is intended to be used:
  i. "May be used in residential facilities, schools, office premises, and non-healthcare settings"
  ii. "Can be used in households, commercial, and institutional settings, such as: homes, professional offices, schools, cafeterias (both in healthcare or non-healthcare settings), garages, gyms, playground and play areas."
- Claim language for Virucide use directions should follow a header such as, "USE DIRECTIONS for VIRUCIDES ONLY".
- For products with only sanitizer claims that are seeking a virucidal claim (not a disinfection claim), language such as: "Kills bacteria AND viruses*", Sanitizer, Virucide*/Virucidal*, "For residential, commercial and/or industrial use", are acceptable.
  i. Note: Claims including a reference to viruses (such as those denoted with the asterisk in the example above) should be qualified on label with a list of specific viruses tested for efficacy and submitted to the Agency for review.

- The following are examples of claims that would generally **not be acceptable** on the label of a product containing sanitizer only claims seeking addition of virucidal claims:

  i. "Kills germs" – as this term is too broad and should be used only on products with efficacy data against viruses, bacteria and fungi. See the following for additional information: https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels.

  ii. Unqualified virus claims - all claims regarding killing viruses should be qualified (e.g., marked with an asterisk that links to the list of viruses) with specific viruses tested for efficacy and submitted to the Agency for review.

  iii. "For use in hospital or healthcare settings" – Use sites for sanitizers should be limited to non-patient care associated settings, even if virus claims are present.

Attachment 1: Example Terms of Registration for Registrants Adding Virucidal Claims to a Product Bearing only Sanitizer Claims

Terms of Registration Associated with the Guidance for
Making Claims against Viruses on EPA Registered Sanitizer Labels

Per the Interim Guidance for the Evaluation of Products for Claims against Viruses, **[Company Name]** agrees to submit a notification pursuant to Pesticide Registration Notice 98-10 and 40 C.F.R. § 152.46 no later than **[DATE]** to remove from **[Product Name], [EPA Reg. No.]** no later than **[DATE 60 DAYS AFTER SUBMISSION OF THE NOTIFICATION]** the following virucidal claims for use on hard, non-porous surfaces in non-healthcare settings only:

1. [Virus Name], [ATCC #]
2. [Virus Name], [ATCC #]
3. [Virus Name], [ATCC #]

The above specified claims will not need to be removed if the Agency decides to make the policy permanent prior to the end of the 10 year period.

[Insert Company Rep Signature]

[Date]