



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 12, 2021

Mr. Peter Tolsdorf
General Counsel and Secretary
National Electrical Manufacturers Association
1300 17th St N, Suite 900
Arlington, VA 22209

Dear Mr. Tolsdorf:

Thank you for your December 22, 2020 letter seeking written guidance to confirm that manufacturers or importers of ultraviolet lights (UV lights) may use certain generic efficacy claims for all UV light products. In particular, you seek confirmation that such manufacturers and importers could: 1) identify such lights as “germicidal lights;” (2) state on product literature and product packaging that UV light is “effective against most viruses, spores and cysts;” and (3) make claims of a similar general nature involving bacteria, fungi, and other pathogens as supported by scientific research and consensus. The U.S. Environmental Protection Agency (EPA) does not routinely review the safety or efficacy of pesticidal devices subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including UV light products, and cannot confirm whether—or under what circumstances—such products might be effective. Each device has a unique design and intended operation and for this reason, EPA assesses claims on a case-by-case basis. Therefore, EPA does not support the use of generic efficacy claims.

While there are no pre-market reviews of pesticide devices, or associated efficacy studies, each device manufacturer or importer must be able to substantiate claims made on its labeling and marketing materials. *See* 40 C.F.R. § 152.500, 40 C.F.R. pt. 169. The efficacy of any UV light device depends on a variety of factors including the device’s duration of use, the effective distance of the light for the intended pesticidal purpose, the UV wavelength, the specific pest being targeted, the strength or wattage of the UV light bulb, the age of the UV light bulb, and shadow areas, among other factors.

EPA assesses device labeling claims on a case-by-case basis. EPA considers claims such as “germicidal lights” and “effective against most viruses, spores or cysts” to be false and misleading unless they are appropriately qualified on labeling and supported by the product’s efficacy testing. If claims are made against specific pathogens, EPA maintains that testing of the device against those pathogens on the specific substrate (*e.g.*, *E. coli* on cloth) is necessary to substantiate those claims. For more information on EPA’s regulation of devices, see Chapter 13 of the Pesticide Registration Manual, available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices>. Similarly, EPA considers a claim that a device is “safe” to be false or misleading. *See* 40 C.F.R. §156.10(a)(5)(ix). Furthermore,

the safety of any UV light device depends on a variety of factors including user directions that prevent public health risks—such as electric shock or UV exposure (*e.g.*, to skin or eyes)—and device design, among other factors. Selling or distributing pesticidal devices with false or misleading claims about their safety or efficacy may subject the seller or distributor to enforcement action and penalties under FIFRA.

In your letter, you cite two EPA resources¹ that discuss the applicability of UV light for wastewater treatment as a replacement or supplement to chemical disinfection. Your letter does not specify whether you are supporting label claims for UV light systems intended to treat wastewater or inanimate surfaces and objects. Given the ongoing COVID-19 pandemic and the resulting increase in demand for antimicrobial products that may be used for the latter, EPA maintains that it is important to distinguish between these uses. Wastewater treatment facilities have continuous on-site monitoring and testing capabilities to ensure that any treatments—whether chemicals or UV light systems—remain effective. UV lights sold to residential or institutional users generally do not have the benefit of such on-site monitoring and testing to ensure their efficacy. Further, the statements made regarding the effectiveness of UV light technology were made based on meeting certain efficacy and/or performance criteria. For example, the statement in the 2007 document titled, “Ultraviolet (UV) Disinfection Systems for Secondary Wastewater Effluent and Water Reuse” was made based on meeting the joint EPA/National Sanitary Foundation (NSF) performance criteria established specifically for wastewater treatment systems and providing performance-based validation of the specific systems’ antimicrobial capabilities. UV lights in the consumer marketplace would not have the benefit of EPA/NSF efficacy testing to substantiate product performance claims.

In addition to the wastewater treatment research discussed in your letter, EPA has become aware of numerous instances where UV light purveyors have made reference in their marketing materials to a public webinar on UV lights held by EPA’s Office of Research and Development (ORD) on January 21, 2021. The webinar detailed ORD’s research on the use and effectiveness of UV lights under varying test conditions. However, this discussion does not constitute an endorsement of the effectiveness of individual UV light systems or the technology as a whole. EPA considers references to the aforementioned EPA UV light system wastewater resources, the ORD webinar, or any other reference implying EPA endorsement on product labels or labeling to be false or misleading. *See* 40 C.F.R. § 156.10(a)(5)(v).

Further, certain UV light devices are regulated by both EPA and the Food and Drug Administration (FDA). EPA does not consider import categorization, consistent with FDA requirements, to be product labeling under FIFRA. An FDA requirement to declare these UV lamps as “germicidal lamps” during the importation process does not mean that this claim is acceptable on labels or labeling for all devices that contain a UV lamp. “Germicidal” is an unqualified germ claim. EPA’s guidance regarding unqualified germ claims can be found on

¹ .EPA, *Wastewater Technology Fact Sheet: Ultraviolet Disinfection*, EPA 832-F-99-064, at 2 (1999), <https://www3.epa.gov/npdes/pubs/uv.pdf>. 2 (“UV disinfection is effective at inactivating most viruses, spores, and cysts”); EPA, *Ultraviolet (UV) Disinfection Systems for Secondary Wastewater Effluent and Water Reuse*, EPA/600/S-07/015, at 2 tbl. 2 (2007), <https://archive.epa.gov/nrmrl/archive-etv/web/pdf/p10012zq.pdf>. (noting that advantages of UV disinfection include: “effective at inactivating most bacteria, viruses, spores and cysts”).

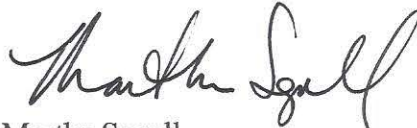
EPA's website at the following URL: <https://www.epa.gov/pesticide-labels/use-term-germs-antimicrobial-labels>.

If you have any further questions, please contact the co-chairs of the Device Determination Work Group, Diane Isbell or Yvette Hopkins at OPPDeviceDeterminations@epa.gov.

Sincerely,



Anita Pease
Director, Antimicrobials Division
Office of Pesticide Programs



Martha Segall
Acting Director, Monitoring, Assistance and Media
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