

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Region III
1650 Arch Street
Philadelphia, Pennsylvania 19103-2029**

IN THE MATTER OF:	:	
	:	
ViaClean Technologies, LLC	:	Docket No. FIFRA-03-2021-0076SS
230 S. Broad Street, Suite 1202	:	
Philadelphia, PA 19102,	:	STOP SALE, USE, OR REMOVAL ORDER
	:	
	:	Proceeding under Section 13(a) of the Federal
	:	Insecticide, Fungicide, and Rodenticide Act
Respondent.	:	
_____	:	

STOP SALE, USE OR REMOVAL ORDER

I. AUTHORITY

1. This Stop Sale, Use or Removal Order (“Order”) is issued to ViaClean Technologies, LLC (“ViaClean” or “Respondent”) pursuant to the authority vested in the Administrator of the U.S. Environmental Protection Agency (“EPA” or the “Agency”) by Section 13(a) of the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”), as amended, 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device to any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that such pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
2. The Administrator of the EPA delegated this authority under FIFRA to the Regional Administrators by the EPA Delegation 5-12. The authority to issue Stop Sale, Use or

Removal Orders has been redelegated to the Director of the EPA Region III Enforcement and Compliance Assurance Division, among other delegates.

II. APPLICABLE LAW

3. Section 3 of FIFRA, 7 U.S.C. § 136a, provides that no person in any State may distribute or sell to any person any pesticide that is not registered under FIFRA.
4. Section 3(c)(1)(C) of FIFRA, 7 U.S.C. § 136a(c)(1)(C), requires that “[e]ach applicant for registration of a pesticide shall file with the Administrator a statement which includes . . . a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use.”
5. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a “person” as “any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.”
6. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a “pesticide” in part, as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”
7. Section 2(t) of FIFRA, 7 U.S.C. § 136(t), defines a “pest” as “any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 136w(c)(1) of this title.”
8. Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), defines an “antimicrobial pesticide” as “(i) a pesticide that is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects, industrial

processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.”

9. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines “to distribute or sell” as “to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.” *See also* 40 C.F.R. § 152.3.
10. Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), provides that it is unlawful for any person in any State to distribute or sell to any person “any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under [Section 3].” *See also* 40 C.F.R. § 168.22.

III. BASIS FOR THE ORDER

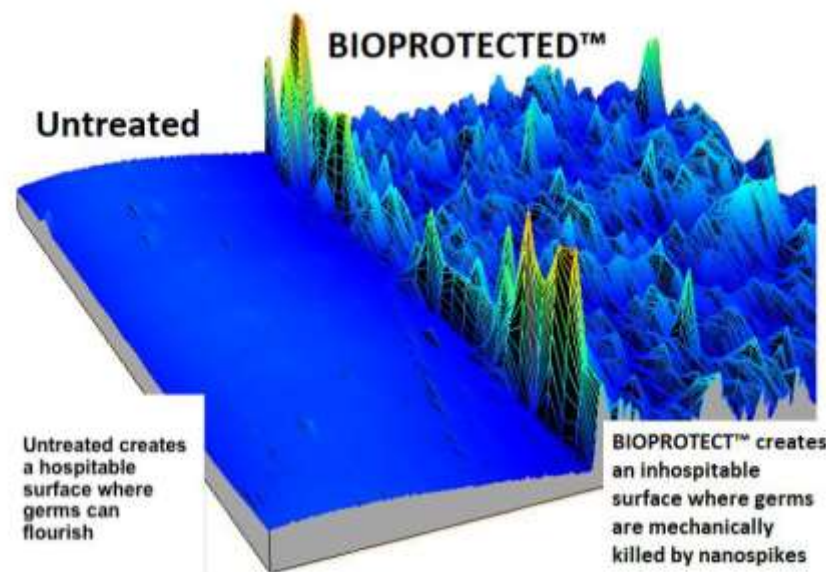
11. The Respondent in this matter is ViaClean Technologies, LLC, a limited liability company with its principle place of business located at 230 S. Broad Street, Suite 1202, Philadelphia, Pennsylvania 19102. ViaClean is a “person” as defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).
12. ViaClean sells and markets the “BioProtect” line of products, which includes among other products, BioProtect RTU.
13. BioProtect RTU is a “pesticide” as that term is defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

14. BioProtect RTU is an alternate brand name of the EPA-registered pesticide BioProtect AM50 (EPA Reg # 87583-3), which is registered pursuant to Section 3 of FIFRA, 7 U.S.C. § 136a.¹
15. BioProtect RTU is EPA-registered to inhibit the growth of odor causing bacteria, bacteria which cause staining and discoloration, fungi (mold and mildew), and algae. A copy of the registered label for BioProtect AM50 (EPA Reg. # 87583-3), alternate brand name of BioProtect RTU, is attached hereto as Attachment 1.
16. In March 2020, the EPA Region III was notified of potential violative claims made by ViaClean regarding its product BioProtect RTU.
17. On October 1, 2020, the EPA Region III sent an Information Request Letter (“IRL”) to ViaClean requesting, among other things, information related to the sale and distribution of their products. A copy of the October 1, 2020 IRL is attached hereto as Attachment 2.
18. On October 29, 2020, Respondent responded to the IRL and within its response, included an advertisement titled “BioProtect RTU”, which Respondent stated has accompanied the distribution and sales of BioProtect RTU to certain persons.²
19. The advertisement referenced in paragraph 18 above, titled “BioProtect RTU”, a copy of which is attached hereto as Attachment 3, contains the following public health claims, which are not included as part of BioProtect RTU’s EPA Registration:
 - a. “Provides persistent, continuous, antimicrobial protection against a broad range of microbes”
 - b. “Prevents the mutation of adaptive microorganisms”

¹ Pureshield, Inc., a subsidiary of ViaClean, is the primary registrant of BioProtect RTU.

² ViaClean designated its response to the EPA’s IRL and the documents contained therein as confidential business information (“CBI”). After a request by the EPA, ViaClean did not object to removal of the CBI designation for the advertisement titled, “BioProtect RTU”.

- c. "...uses self assembling monolayers to create a layer of spikes that mechanically kill microbes (bacteria, mold, mildew & algae) by piercing and rupturing their cell membrane. This kill method prevents microbes from mutating and adapting, inhibiting the ability for superbugs to grow."
 - d. "BIOPROTECT creates an inhospitable surface where germs are mechanically killed by nanospikes."
 - e. "Large Spectrum Efficacy – Effective against a broad spectrum of microbes"
20. Additionally, the EPA observed the image below, and determined that it contains public health claims that are not included as part of BioProtect RTU's EPA Registration, and the image is found in the advertisement "BioProtect RTU" (Attachment 3), as well as several websites of distributors and applicators of BioProtect RTU³:



³ The websites where this image is found include, but are not limited to: Harrisburg Cleaners, <https://www.harrisburgcleaners.com/antimicrobial-surface-protection>; Science, the BioProtect™ Technology, BioProtectors, <https://www.bioprotectors.com/the-science/>; Disinfectant Prevention Services – COVID-19 Corona Virus, Mac's Janitorial Services, <http://www.macsjanitorial.com/services/coronavirus-disinfectant-services-nj-pa/>; BioProtectUS™ System, US Consulting Group, <https://bioprotectsales.com/bioprotectus-system>; About Us – Our

21. Based on inspections of the registered label for BioProtect RTU and the advertisement titled “BioProtect RTU” (Attachment 3), EPA determined that the public health claims made in the advertisement described in paragraphs 19 and 20 above, substantially differ from any claims made for it as a part of the statement required in connection with its registration under Section 3 of FIFRA, 7 U.S.C. § 136a. See also 40 C.F.R. § 168.22.
22. EPA inspected the sales records provided in response to the IRL and determined that they show that ViaClean has distributed or sold BioProtect RTU to at least one person to which it provided the advertisement described in paragraphs 19-20 above.
23. The following are examples of additional public health claims⁴ that the EPA observed on websites belonging to distributors and applicators of BioProtect RTU which are not included as part of BioProtect RTU’s EPA Registration:
 - a. “Superbug preventative”⁵
 - b. “The BIOPROTECTUS System (SMARTTOUCH and BIOPROTECT) creates a barrier on your surface protecting the surface from harmful microbes such as the below bacteria, fungi, and viruses.”⁶
 - c. “Ready to use, water-based antimicrobial surface protectant that kills and inhibits the growth of problematic bacteria, fungi, algae, protozoans and other microorganisms.”⁷

Antimicrobial Protection, Clean Tech Partners, <https://cleantechpartners.net/about-us>; BioSafe Gloves, <https://biosafegloves.com/>.

⁴ The listed examples are not all inclusive of the public health claims found by the EPA related to BioProtect RTU.

⁵ Hospitality & the BioProtectUS™ System, US Consulting Group, <https://bioprotectsales.com/germ-protection-hospitality>.

⁶ Education Facilities & the BioProtectUS™ System, US Consulting Group, <https://bioprotectsales.com/germ-protection-educational>.

⁷ BioProtect™ RTU (Ready to Use), Biodome, <https://biodomeprotection.com/products/bioprotect-rtu?variant=35525563515029>.

- d. “BIOPROTECT™ RTU’s patented antimicrobial technology uses self assembling monolayers to create a field of nanospikes that mechanically kill microbes (bacterias, molds, viruses) by piercing and rupturing their cell membrane. This kill method prevents microbes from mutating and adapting inhibiting the ability for superbugs to grow.”⁸
 - e. “The BIOPROTECTUs™ system uses patented, EPA registered technologies to modify surfaces, providing such surfaces with disinfection and durable long term antimicrobial protection that kills and inhibits the growth of problematic bacteria, fungi, algae, protozoans, viruses and other microorganisms that can exist on many of life’s surfaces. BIOPROTECT™ is a durable, EPA registered, bound antimicrobial technology that protects surfaces for up to 90 days without reapplication. BIOPROTECT™ continues to work while in the dry state and creates a non-receptive surface that physically disrupts and inhibits the growth of incoming microbes.”⁹
24. Upon information and belief, based on the information described in paragraphs 19-23 above, EPA Region III has reason to believe that ViaClean has distributed and sold BioProtect RTU with public health claims that substantially differ from any claims made for it as a part of the statement required in connection with its registration under Section 3 of FIFRA, 7 U.S.C. § 136a to persons.

⁸ The BioProtect™ Products, BioProtectors, <https://www.bioprotectors.com/products/bioprotect-rtu/>.

⁹ About Us – Our Antimicrobial Protection, Clean Tech Partners, <https://cleantechpartners.net/about-us>.

IV. SUMMARY BASIS FOR THE ORDER

25. In light of the findings set forth above in paragraphs 11 through 24 above, upon information and belief, EPA Region III has reason to believe that BioProtect RTU has been distributed, sold, and/or offered for sale by ViaClean in violation of 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B).

V. ORDER

26. Pursuant to the authority of Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders ViaClean to **immediately cease** the sale, use, or removal of BioProtect RTU that are labeled or marketed with public health claims that substantially differ from any claims made for it as a part of the statement required in connection with its registration under Section 3 of FIFRA 7 U.S.C. § 136a (“the Violative Products”) under its ownership, custody, or control, except in compliance with the provisions of this Order.
27. The Violative Products shall not be sold; offered for sale; held for sale; shipped; delivered for shipment; received; or having been so received; delivered; offered for delivery; moved or removed from wherever the products are located, by ViaClean for purposes of distribution and/or sale of the product to any person, without prior written approval from the EPA. ViaClean shall not make any claims about BioProtect RTU as a part of the distribution or sale of the product that substantially differ from any claims made for it as a part of the statement required in connection with its registration.

ViaClean shall send all written request(s) for approval to:

Hannah G. Leone
Assistant Regional Counsel
EPA, Region 3
Office of Regional Counsel
Leone.hannah@epa.gov

28. This Order applies to all quantities, unit sizes and forms of the Violative Products intended for distribution and/or sale within the ownership, control, or custody of ViaClean, or under the ownership, control, or custody of any person acting for ViaClean, wherever located in the United States, or that may come into the possession of ViaClean, related to the Violative Products.
29. Violation of the terms or provisions of this Order may subject ViaClean to civil penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136*l*.
30. The issuance of this Order shall not constitute a waiver by EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
31. This Order shall be EFFECTIVE IMMEDIATELY upon receipt by ViaClean.
32. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by the EPA.
33. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not be affected or impaired thereby and they shall remain in full effect.
34. EPA may amend this Order and Attachments 1 through 3 at any time to include additional distributions and/or sales of BioProtect RTU, in violation of FIFRA, or additional pesticides or devices that EPA has a reason to believe ViaClean is distributing or selling, or intends to distribute or sell, in violation of FIFRA.
35. ViaClean may seek federal judicial review of the Order pursuant to Section 16 of FIFRA, 7 U.S.C. § 136*n*.

IV. OTHER MATTERS

36. For any additional information about this Order, please contact Holly Raguza, Compliance Officer, at (215) 814-2170. For any legal matters concerning this Order, including questions from legal counsel, please contact Hannah Leone, Assistant Regional Counsel, at (215) 814-2673.

Date

Karen Melvin, Director
Enforcement & Compliance Assurance Division
U.S. EPA – Region III