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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

EPA Region VIII Hearing Clerk

IN THE MATTER OF:)	
)	Docket No. FIFRA-08-2021-0027
PURE MAINTENANCE OF)	
COLORADO LLC)	FIFRA SECTION 13(a)
4885 Marshall Street Suite 106)	
Wheat Ridge, Colorado 80033-3658)	STOP SALE, USE, or
)	REMOVAL ORDER
)	
Respondent.)	
)	
)	
)	

I. <u>AUTHORITY</u>

- 1. This Stop Sale, Use, or Removal Order (Order) is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency (EPA) by section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), 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 by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that the 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 undersigned EPA official has been duly authorized to issue this Order.¹

II. GOVERNING LAW

- 3. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), provides that it shall be unlawful for any person in any State to distribute or sell to any person any pesticide that is not registered under Section 3 of FIFRA, 7 U.S.C. § 136.
- 4. Section 3(a) of FIFRA, 7 U.S.C. § 136a(a), provides that, "Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter..." See also, 40 C.F.R. § 152.15.

¹ See EPA Administrator Delegation of Authority 5-12. Issuance of Stop Sale Use or Removal Orders (1200 TN 350 5-12) (Jan. 18, 2017); R8 Redelegation (Apr. 29, 2019); Division Director Redelegations (Sept. 5, 2019); Branch Chief Redelegations (Sept. 19, 2019).

- 5. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it shall be unlawful for any person in any State to distribute or sell to any person any pesticide which is adulterated or misbranded."
- 6. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136j(a)(2)(S), provides that it shall be unlawful for any person to violate any regulation issued under section 3(a) or 19 of FIFRA.
- 7. 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."
- 8. Section 2(t) of FIFRA, 7 U.S.C. § 136(t) defines "pest" in part, as any "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 25(c)(1)."
- 9. Pursuant to the authority in Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator declared that a pest is, "[a]ny fungus, bacterium, virus, prion, or other microorganism, except for those on or in living man or other living animals and those on or in processed food or processed animal feed, beverages, drugs... and cosmetics...." 40 C.F.R. § 152.5(d).
- 10. 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[.]"
- 11. The EPA's implementing regulations at 40 C.F.R. § 152.15 provides that, "a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose..." and that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if:
 - (a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):
 - (1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or
 - (2) That the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or
 - (b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for pesticidal purpose (by itself or in combination with any other substance), (2) use for manufacture of a pesticide; or
 - (c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.
- 12. 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."

- 13. The regulation at 40 C.F.R. § 152.3 further defines the term "distribute or sell" as "the acts of distributing, selling, offering for sale, holding for sale, shipping, holding for shipment, delivering for shipment, or receiving and (having so received) delivering or offering to deliver, or releasing for shipment to any person in any State."
- 14. Section 2(e) of FIFRA, 7 U.S.C. § 136(e), provides that, "[....] Any applicator who holds or applies registered pesticides, or uses dilutions of <u>registered</u> pesticides consistent with [FIFRA Section 2(ee], only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this subchapter." (emphasis added).
- 15. Section 2(e) of FIFRA applies only to the use of <u>registered</u> pesticides. Those who sell or distribute <u>unregistered</u> pesticides remain subject to the prohibitions under Section 12(a) of FIFRA, 7 U.S.C. § 136j(a). This includes persons who offer to sell, hold, or apply an unregistered pesticide. Accordingly, any applicator, including a "for hire" applicator, who holds or applies an unregistered pesticide to provide a service of controlling pests without delivering any unapplied pesticide will be considered a seller or distributor of pesticides and will be subject to the higher penalties set forth in Sections 14(a)(1) and 14(b)(1) of FIFRA. See also, 44 Fed. Reg. 33151, 33152 (June 8, 1979).
- 16. Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), provides that, "antimicrobial pesticides" are pesticides that are "intended to (i) 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[.]"
- 17. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines "label" as "the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers" and defines "labeling" in part, as "all labels and all other written, printed, or graphic matter (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide...."
- 18. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, "a pesticide is misbranded if
 - [a] its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
 - [b] it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;
 - [c] it is an imitation of, or is offered for sale under the name of, another pesticide;
 - [d] its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;
 - [e] any word, statement, or other information required by or under the authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as

compared to other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

- [f] the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment; [or]
- [g] the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment[.]"
- 19. In accordance with 40 C.F.R. § 156.10(a)(5), a pesticide is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:
 - a. A false or misleading statement concerning the effectiveness of the product as a pesticide or device. 40 C.F.R. § 156.10(a)(5)(ii);
 - b. Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government. 40 C.F.R. § 156.10(a)(5)(v); and
 - c. A true statement used in such a way as to give a false or misleading impression to the purchaser. 40 C.F.R. § 156.10(a)(5)(vii).
- 20. The regulation at 40 C.F.R. § 156.10(a)(1) provides that, "[e]very pesticide product shall bear a label containing the information specified by [FIFRA] and the regulations in this part." The contents of a label must show clearly and prominently the following: (i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section; (ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section; (iii) The net contents as prescribed in paragraph (d) of this section; (iv) The product registration number as prescribed in paragraph (e) of this section; (v) The producing establishment number as prescribed in paragraph (f) of this section; (vi) An ingredient statement as prescribed in paragraph (g) of this section; (vii) Hazard and precautionary statements s prescribed in subpart D of this part for human and domestic animal hazards and subpart E of this part for environmental hazards. (viii) The directions for use as prescribed in paragraph (i) of this section; and (ix) The use classification(s) as prescribed in paragraph (j) of this section.
- 21. The regulation at 40 C.F.R. § 156.10(b)(2) provides that, "No name, brand, or trademark may appear on the label which: (i) Is false or misleading, or (ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 152.132."
- 22. The regulation at 40 C.F.R. § 156.10(f) provides that, "The producing establishment registration number preceded by the phrase 'EPA Est.', of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on

- the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container."
- 23. Under 40 C.F.R. § 152.132, a registrant may distribute or sell a registered product under another person's name and address under a "supplemental distribution." The distributor is considered an agent of the registrant for all intents and purposes under the Act and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to the EPA if all the following conditions are met:
 - (a) The registrant has submitted to the Agency for each distributor product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand name(s) to be used, and the registration number of the registered product.
 - (b) The distributor product is produced, packaged and labeled in a registered establishment operated by the same producer (or under contract in accordance with §152.30) who produces, packages, and labels the registered product.
 - (c) The distributor product is not repackaged (remains in the producer's unopened container).
 - (d) The label of the distributor product is the same as that of the registered product, except that:
 - (1) The product name of the distributor product may be different (but may not be misleading);
 - (2) The name and address of the distributor may appear instead of that of the registrant;
 - (3) The registration number of the registered product must be followed by a dash, followed by the distributor's company number (obtainable from the EPA upon request);
 - (4) The establishment number must be that of the final establishment at which the product was produced; and
 - (5) Specific claims may be deleted provided that no other changes are necessary.

III. BASIS FOR THE ORDER

- 24. Pure Maintenance of Colorado LLC (Respondent) is a limited liability company organized under the laws of the State of Colorado and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s) and subject to FIFRA and the implementing regulations promulgated thereunder.
- 25. Respondent provides disinfection, sanitization, and mold remediation services in commercial and residential settings using, among other things, a dry fogging system licensed to Respondent by Pure Maintenance Holdings, LLC (PMH) of Layton, Utah.

- 26. PMH licenses its "Pure Maintenance system" to Respondent and other entities, which it claims is a "patented" two-step dry fogging system (via a certain type of fogger that does not wet surfaces). The dry-fogging system incorporates the use of products called "InstaPURE" and "EverPURE."
- 27. PMH claims, in online statements and in statements made to Respondent, that its dry fogging system using **InstaPURE** and **EverPURE** disinfects and sterilize any surface and kills mold, viruses (including SARS-CoV-2, the novel human Coronavirus), and bacteria on surfaces treated surfaces. The products are used sequentially in the two-step dry fogging process and are marketed together for the system.
- 28. In some cases, the dry fogging system incorporates the use of antibacterial wipes that are on EPA's List-N as part of a "wipe down" service; this is referred to as a three-step process.
- 29. In March 2020, the EPA released its initial *List N: Disinfectants for Use Against SARS-CoV-2* (List N). EPA's List N is a listing of surface disinfectant products that meet the EPA's criteria for effectiveness against SARS-CoV-2 (the novel coronavirus that causes COVID-19) when used according to the EPA accepted label directions.

EPA's Observation of Respondent's Dry Fogging System

- 30. On July 29, 2020, an EPA-credentialed inspector conducted a non-agriculture pesticide use inspection at two locations: a commercial location that had hired Respondent for its application services and then, immediately following, at Respondent's principal place of business, 4885 Marshall Street Suite 106, Wheat Ridge, Colorado 80033 ("the Facility").
- 31. During the use inspection, the EPA inspector observed Respondent applying two products labeled **InstaPURE** and **EverPURE**, which Respondent described as a "patented" dry fogging system that is part of its normal application service. At the Facility, the EPA inspector observed **InstaPURE** and **EverPURE** product containers and labels (container and label descriptions below). The EPA inspector collected samples of container labels for both **InstaPURE** and **EverPURE** products, sales invoices for Respondent's application services involving the use of **InstaPURE** and **EverPURE**, and the sales invoice for the application observed earlier at the commercial location.
- 32. Based on the invoices EPA collected and reviewed, between May 27, 2020 and July 29, 2020, Respondent had performed at least ten applications, using PMH's licensed two-step dry fogging system applying **InstaPURE** and **EverPURE**.
- 33. Some of the invoices reviewed by the EPA include a third step involving a wipe-down of surfaces with an N-List product. The invoice for the application observed during the inspection on July 29, 2020 also referenced this third step. However, during its July 29, 2020 inspection, the EPA inspector did not observe this step being performed.
- 34. The invoices reviewed by the EPA included a statement that **EverPURE** was used for the following purpose: "EPA verified 90 days of microbial protection with application of EverPURE." These invoices also included Respondent's website address.

- 35. Concurrently with the in-person inspection, the EPA also inspected and collected evidence of online marketing and advertisements published by Respondent on Respondent's website and Facebook pages.
- 36. The EPA's inspection of online materials demonstrates that Respondent's website contains various pesticidal claims including, "Eliminate all existing threats and protect your surfaces from microbial contamination for an EPA-verified 90 days." https://puremaintenanceco.com/ (date visited: Oct. 23, 2020.)
- 37. Respondent made the following claims online regarding its two-step dry fogging system, through which it applied the products labeled as **InstaPURE** and **EverPURE**, stating on its website (https://puremaintenanceco.com/) and Facebook page (https://www.facebook.com/PureMaintennceCO/):
 - "PREVENTATIVE MAINTENANCE AGAINST VIRUSES

Using our patent-protected dry fog technology, and the application of our N-list disinfectant InstaPURE (EPA Reg. # 70299-19), we obliterate the presence of viruses, including the human coronavirus causing COVID-19.

For additional peace of mind (and for a slight upcharge), we can follow our InstaPURE dry fog application with an additional EPA-registered N-List product wipedown for high-touch surfaces for, then cap it all off with the application of EverPURE, a low-level disinfectant with electrostatic antimicrobial properties. We call this three-step process the "VIRUS SCRUB."

The Novel Coronavirus (SARS-CoV-2) is an "enveloped virus." Both InstaPURE and EverPURE are sufficient to denature enveloped viruses and non-enveloped viruses like H1N1, avian flu, and noroviruses, and they require very little dwell time. An entire building can typically be treated in one day and provide safety for anyone worried about getting the virus. While preventative treatment of a facility will not prevent person-to-person infections and does not replace the need to wear a facemask and wash your hands, it will help prevent surface-to-person infections." https://puremaintenanceco.com/covid-19 (last visited February 3, 2021).

"1ST STEP IN OUR PROCESS INSTAPURE KILLS ALL BACTERIA IN HOME Our patented 2-step process removes all bacteria from a home in just 4 hours! Our first step InstaPURE, fills the home with our Dry Fog. This will kill all mold, bacteria, virus and pathogens!" Facebook post dated April 28, 2020, https://m.facebook.com/photo.php?fbid=750594689092756&id=342538666565029&set=

<u>a.414588322693396&source=54</u> (last visited February 3, 2021).

38. During the July 29, 2020 inspection, Respondent informed the EPA inspector that PMH provides its licensees with, among other things: containers of product labeled **InstaPURE** and **EverPURE**; the Pure Maintenance two-step dry fogging systems; promotional materials advertising these products; and access to its internal website.

- 39. As a licensee of PMH, Respondent offers and applies the Pure Maintenance two-step dry fogging system using **InstaPURE** and **EverPURE**.
- 40. Neither PMH nor Respondent operates a "registered establishment" for the purposes of producing, packaging, or labeling pesticidal products, as that term is defined in 7 U.S.C. § 136e(a).
- 41. SARS-CoV-2, the novel coronavirus that causes COVID-19 (the "novel coronavirus"), is a "pest" within the meaning of section 2(t) of FIFRA, 7 U.S.C. § 136(t).

InstaPURE Pesticide

- 42. PMH entered into a supplemental distributor agreement with Biosafe Systems, LLC, the registrant of **Sanidate 5.0**, EPA Registration Number ("EPA Reg. No.") 70299-19 (**Sanidate**), to distribute **Sanidate** under the distributor product name **InstaPURE**, EPA Reg. No. 70299-19-95371.
- 43. **Sanidate** was added to EPA's List N on July 7, 2020. Prior to July 7, 2020, **Sanidate** was not on List N and therefore was not approved by the EPA for use against the novel coronavirus.
- 44. The EPA-accepted label for **Sanidate**, dated July 7, 2020, provides the following:
 - "For general information on this product, contact the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC website: www.npic.orst.edu). For medical emergencies, call the poison control center at 1-800-222-1222."
 - "PERSONAL PROTECTIVE EQUIPMENT (PPE) Handlers who may be exposed to the product through mixing, loading, application, or other tasks must wear: coveralls over long-sleeved shirt and long pants, rubber gloves, chemical resistant footwear plus socks, and protective eyewear (goggles or face shield). Follow manufacturer's instructions for cleaning / maintaining PPE. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."
 - "USER SAFETY RECOMMENDATIONS Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."
 - "ALL SURFACES MUST BE THOROUGHLY PRE-CLEANED PRIOR TO FOGGING....
 This product may be applied by fogging to control the growth of non-public health
 microorganisms that cause decay and spoilage on hard, non-porous surfaces in food
 premises." (Emphasis added.)
 - "FOR USE AS A VIRUCIDE AGAINST HUMAN COROAVIRUS This product kills the following virus [...] when applied to hard, non-porous surfaces: *Human Coronavirus* [...] Apply use solution to hard, non-porous surfaces using a sponge, brush, cloth, mop, by immersion or coarse spray device. [...] Treated surfaces must remain visibly wet for ten (10) minutes." (Emphasis added.)

- 45. The **Sanidate** label dated July 7, 2020 does <u>not</u> indicate that fogging may be used as an application method for use against viruses.
- 46. The prior EPA-accepted label for **Sanidate**, dated March 25, 2020, provides the following:
 - "For general information on this product, contact the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC website: www.npic.orst.edu). For medical emergencies, call the poison control center at 1-800-222-1222."
 - "PERSONAL PROTECTIVE EQUIPMENT (PPE) Handlers who may be exposed to the product through mixing, loading, application, or other tasks must wear: coveralls over long-sleeved shirt and long pants, rubber gloves, chemical resistant footwear plus socks, and protective eyewear (goggles or face shield). Follow manufacturer's instructions for cleaning / maintaining PPE. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."
 - "USER SAFETY RECOMMENDATIONS Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."
 - "ALL SURFACES MUST BE THOROUGHLY PRE-CLEANED PRIOR TO FOGGING.
 This product may be applied by fogging to control the growth of non-public health microorganisms that cause decay and spoilage on hard, non-porous surfaces in food premises." (Emphasis added.)
 - "GENERAL DISINFECTION This product is not to be used for the disinfection of surfaces made of wood. VIRICIDAL When used at the disinfectant rate of 0.5 to 2.2 fl. oz. per gallon of water, SaniDate 5.0 is an effective viricide against: *Human Influenza Virus* (H1N1)[,] Canine Distemper[, and] Virus Avian Influenza Virus (H9N2)"
 - "DISINFECTION Use SaniDate 5.0 as a disinfectant at a dilution rate of 1:256 1:50 (0.5 2.2 fl. oz. per gallon of water), (230 1,000 ppm of peroxyacetic acid). Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. <u>Treated surfaces must remain visibly wet for ten (10) minutes</u>." (Emphasis added.)
- 47. The **Sanidate** label dated March 2020 also does <u>not</u> indicate that fogging may be used as an application method for use against viruses.
- 48. Prior to the March 2020 label, the EPA-accepted label for **Sanidate**, dated October 24, 2019, provided the same information quoted above for the March 25, 2020 **Sanidate** label; the October 24, 2019 label also does <u>not</u> indicate that fogging may be used as an application method for use against viruses.

- 49. At the July 29, 2020 inspection, Respondent possessed **InstaPURE** containers with labels that were different than the **Sanidate** label registered with the EPA in numerous respects, EPA inspected the labels and observed the following differences:
 - The **InstaPURE** label does not contain the following language: "For general information on this product, contact the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC web site:www.npic.orst.edu). For medical emergencies, call the poison control center at 1-800-222-1222."
 - The InstaPURE label does not contain PPE specifications and did not include the following language: "PERSONAL PROTECTIVE EQUIPMENT (PPE) Handlers who may be exposed to the product through mixing, loading, application, or other tasks must wear: coveralls over long-sleeved shirt and long pants, rubber gloves, chemical resistant footwear plus socks, and protective eyewear (goggles or face shield). Follow manufacturer's instructions for cleaning / maintaining PPE. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."
 - The InstaPURE label does not contain the following language: "USER SAFETY RECOMMENDATIONS Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."
- 50. At the July 29, 2020 inspection, Respondent possessed **InstaPURE** containers with labels that listed multiple production establishments with boxes in front of each establishment that were meant to be checked off; but no box was checked on the **InstaPURE** labels. Because no box was checked, the labels did not include the producing establishment registration number of the final establishment at which the product was produced.
- 51. Based on the PMH license and the supplemental distributor agreement for **Sanidate**, **InstaPURE** is intended to be used as a pesticide, and thus is a "pesticide" within the meaning of section 2(u) of FIFRA, 7 U.S.C. § 136(u) and 40 C.F.R. § 152.15.
- 52. The claims on Respondent's website and Facebook page are pesticidal claims and they also demonstrate that **InstaPURE** is a "pesticide" within the meaning of section 2(u) of FIFRA, 7 U.S.C. § 136(u) and 40 C.F.R. § 152.15.
- 53. The EPA has reason to believe that the **InstaPURE** products within Respondent's possession and applied during Respondent's dry fogging system are pesticides that are not registered with the EPA based on the inspections described above and EPA's review of information collected concurrently with those inspections.
- 54. Based on its labeling and production, **InstaPURE** does not meet the conditions for supplemental distribution under 40 C.F.R. § 152.132(b), (c), or (d) for **Sanidate** and is not otherwise registered with the EPA; therefore, **InstaPURE** is a pesticide that is not registered pursuant to section 3 of FIFRA, 7 U.S.C. § 136a.

- 55. Based on the invoices received at the July 29, 2020 inspection and information collected from Respondent's website and Facebook pages, Respondent distributed or sold and continues to offer for distribution or sale **InstaPURE** as defined by section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
- 56. Therefore, the EPA has reason to believe Respondent distributed or sold the unregistered pesticide, **InstaPURE**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 57. The EPA also has reason to believe that the **InstaPURE** products within Respondent's possession and applied during Respondent's dry fogging system are misbranded based on the inspections and documentation collected, as detailed above.
- 58. Based on **InstaPURE**'s status as an unregistered pesticide, inclusion of an EPA registration number on the label makes the product misbranded, as defined by Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A) and 40 C.F.R. § 156.10(a)(5), because a registration number implies that a pesticide is registered, which is false or misleading when the pesticide is not registered.
- 59. Because the **InstaPURE** products found were unregistered, label claims regarding efficacy of the product are also false or misleading and the product is misbranded as defined by Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(A)(1) and 40 C.F.R. § 156.10(a)(5), because such claims had not been registered with the EPA.
- 60. In claims made on Respondent's website (which were referred to on invoices accompanying the pesticides and made as part of the distribution and sale of **InstaPURE**), Respondent stated that **InstaPURE** was effective against the Human Coronavirus when applied as a fog; such claims have not been accepted by the EPA and thus are false and misleading, which means the product is misbranded as defined by Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(A)(1) and 40 C.F.R. § 156.10(a)(5).
- 61. At the July 29, 2020 inspection, Respondent had **InstaPURE** containers that did not include the producing establishment registration number (EPA Est.) of the final establishment at which the product was produced, which means the product is misbranded as defined by Section 2 of FIFRA, 7 U.S.C. § 136(q)(2)(C)(i) and 40 C.F.R. §§ 156.10(a)(1)(v) and 156.10(f).
- 62. Therefore, the EPA has reason to believe Respondent distributed or sold and continues to offer for distribution or sale the misbranded pesticide, **InstaPURE**, in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

EverPURE Pesticide

- 63. The product labeling (including websites) offering the **EverPURE** product for sale contain the following pesticidal claims:
 - "PREVENTATIVE MAINTENANCE AGAINST VIRUSES

Using our patent-protected dry fog technology, and the application of our N-list disinfectant InstaPURE (EPA Reg. # 70299-19), we obliterate the presence of viruses, including the human coronavirus causing COVID-19.

For additional peace of mind (and for a slight upcharge), we can follow our InstaPURE dry fog application with an additional EPA-registered N-List product wipedown for high-touch surfaces for, then cap it all off with the application of EverPURE, a low-level disinfectant with electrostatic antimicrobial properties. We call this three-step process the "VIRUS SCRUB."

The Novel Coronavirus (SARS-CoV-2) is an "enveloped virus." Both InstaPURE and EverPURE are sufficient to denature enveloped viruses and non-enveloped viruses like H1N1, avian flu, and noroviruses, and they require very little dwell time. An entire building can typically be treated in one day and provide safety for anyone worried about getting the virus. While preventative treatment of a facility will not prevent person-to-person infections and does not replace the need to wear a facemask and wash your hands, it will help prevent surface-to-person infections." https://puremaintenanceco.com/covid-19 (last visited February 3, 2021).

• "STEP 2: EverPURE

This antimicrobial compound is designed to attract and break down any new mold or bacteria, preventing future growth. EverPURE provides an EPA verified 90 days of protection once applied. The microscopic barrier created by EverPURE leaves no tangible residue, but sits on your keyboards, walls, door knobs, and every other surface silently awaiting the next microorganism to come within its fatal magnetic reach." https://www.puremaintenanceco.com/mold-remediation (last visited February 4, 2021).

- 64. Invoices accompanying the sale of **EverPURE** made the following pesticidal claim: "Sterilization & Preventative Maintenance Commercial Disinfection and Prevention Virus Scrub Disinfection of commercial building using InstaPURE to eliminate all existing viruses. EPA-verified 90 days of microbial protection with application of EverPURE."
- 65. Based on the pesticidal claims above, **EverPURE** is a "pesticide" within the meaning of section 2(u) of FIFRA, 7 U.S.C. § 136(u) and 40 C.F.R. § 152.15 and must be registered with the EPA.
- 66. Respondent's **EverPURE** product has never been registered with the EPA.
- 67. **EverPURE** is also not on EPA's List N, and therefore, not approved by the EPA for use against the novel coronavirus.
- 68. At the July 29, 2020 inspection, the EPA inspector observed that Respondent had **EverPURE** containers of two different sizes: 8 ounces and 5 gallons.
- 69. The EPA inspector observed that neither size of EverPURE container had FIFRA compliant labels.
 - The 8 ounce **EverPURE** containers only bore the following words:

EVERPURE 8oz A Pure Maintenance Product Not Labeled For Resale For use by Pure Maintenance affiliates only

• The 5-gallon **EverPURE** container bore only UPS Ground shipping labels from "Pure Maintenance Shipping Cent," Layton, Utah to Respondent and the following words:

PURE MAINTENANCE
EVERPURE
BIOPROTECT AM500
5 GALLONS
90 DAYS OF PROTECTION
EPA#87583-5
NOT LABELED FOR RETAIL SALE, FOR PURE MAINTENANCE LICENSEES ONLY

- 70. Based on the invoices received at the July 29, 2020 inspection and based on the evidence available on Respondent's website and Facebook pages, Respondent distributed or sold and continues to offer for distribution or sale **EverPURE** as defined by section 2(gg) of FIFRA, 7 U.S.C. § 136(gg).
- 71. Therefore, the EPA has reason to believe Respondent distributed or sold, and continues to offer for distribution or sale, an unregistered pesticide, **EverPURE**, in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 72. The **EverPURE** containers that did not include the producing establishment registration number (EPA Est.) of the final establishment at which the product was produced, in violation of Section 2 of FIFRA, 7 U.S.C. §§ 136(1)(D) 136(q)(2)(C)(i) and 40 C.F.R. §§ 156.10(a)(1)(v) and 156.10(f).
- 73. The **EverPURE** containers were misbranded pursuant to 40 C.F.R. § 156.10(a)(1)(E) because "any word, statement, or other information required under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."
- 74. The **EverPURE** containers were misbranded pursuant to 40 C.F.R. § 156.10(a)(1)(G) because "the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment".
- 75. The **EverPURE** containers were misbranded pursuant to 40 C.F.R. § 156.10(a)(2)(A) because "the label does not bear an ingredient statement on that art of the immediate container (and on the outside or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase...".
- 76. The **EverPURE** containers were misbranded pursuant to 40 C.F.R. § 156.10(a)(2)(B) because "the labeling does not contain a statement of the use classification under which the product is registered".

- 77. The **EverPURE** containers were misbranded pursuant to 40 C.F.R. § 156.10(a)(2)(C) because "there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—(1) the name and address of the producer, registrant, or person for whom produced; (ii) the name, brand, or trademark under which the pesticide is sold;... and (iv) when required by regulation of the Administrator to effectuate the purposes of this subchapter, the registration number assigned to the pesticide under this subchapter, and the use classification..."
- 78. The **EverPURE** containers were misbranded because the label does not bear the "name, brand, or trademark under which the product is sold as prescribed in [40 C.F.R. § 156.10(b)]" as required by 40 C.F.R. § 156.10(a)(i).
- 79. The **EverPURE** containers were misbranded because the label does not bear the "product registration number as prescribed in [40 C.F.R. § 156.10(e)]" as required by 40 C.F.R. § 156.10(a)(iv).
- 80. The **EverPURE** containers were misbranded because the label does not bear an "ingredient statement as prescribed in [40 C.F.R. § 156.10(g)]" as required by 40 C.F.R. § 156.10(a)(vi).
- 81. The **EverPURE** containers were misbranded because the label does not bear the "directions for use as prescribed in [40 C.F.R. § 156.10(i)]" as required by 40 C.F.R. § 156.10(a)(viii).
- 82. The **EverPURE** containers were misbranded because the label does not bear the "use classification as prescribed in [40 C.F.R. § 156.10(i)]" as required by 40 C.F.R. § 156.10(a)(ix).
- 83. Therefore, the EPA has reason to believe Respondent distributed or sold, and continues to offer for distribution or sale, a misbranded pesticide, **EverPURE**, in violation of sections 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).
- 84. Therefore, based on the findings above, the EPA has reason to believe **InstaPURE** and **EverPURE** are pesticides that are not registered and are misbranded, and Respondent has distributed or sold these pesticides, in violation of sections 12(a)(1)(A) and (E) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and (E).

IV. ORDER

- 85. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), the EPA hereby orders Respondent to immediately cease the sale, use, or removal of **InstaPURE** and **EverPURE**, under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
- 86. This Order extends to all quantities of **InstaPURE** and **EverPURE**, intended for sale or distribution, and any stocks returned to Respondent from its sellers, customers, or other end users.
- 87. **InstaPURE** and **EverPURE**, shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, or offered for delivery.

- 88. Respondent may move or remove any **InstaPURE** and **EverPURE**, from any facility or establishment ONLY after obtaining prior written approval from the EPA, in accordance with the following:
 - Movement or removal requests must be made in writing addressed to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1595 Wynkoop Street, Denver, Colorado 80202, or at tokarz.christine@epa.gov.
 - Any request for movement or removal must include a written accounting of the
 products to be moved, the address of the facility from which the products will be
 moved, the address of the destination facility, and a description of the reasons for
 the movement or removal.
 - If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to the EPA and the disposal must comply with all applicable federal, state, and local laws.
 - Any movement or removal of any InstaPURE or EverPURE, made without prior
 written authorization from the EPA in accordance with this paragraph constitutes
 a violation of this Order and distribution and sale of illegal pesticides in violation
 of FIFRA.
- 89. Within 30 days of receipt of this Order, Respondent must submit to the EPA a written accounting of InstaPURE and EverPURE subject to this Order. The accounting must be submitted to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, 1595 Wynkoop Street, Denver, Colorado 80202, or at tokarz.christine@epa.gov, and must include an accounting of all existing product inventory, including the locations(s) where the products are held, quantities, and container sizes. Respondent must provide the EPA with an updated accounting at least every 30 days following receipt of this order until Respondent no longer has any InstaPURE or EverPURE, in its ownership, custody or control.
- 90. The information requested in paragraphs 88 and 89 must be provided to the EPA regardless of whether Respondent regards part or all of it as a trade secret or confidential business information. Respondent is entitled to assert a claim of business confidentiality covering all or any required information, in the manner described at 40 C.F.R. section 2.203(b) by labeling such information at the time it is submitted to the EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a claim of business confidentiality will be disclosed by the EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. Unless Respondent makes a claim at the time that it submits the information in the manner described in 40 C.F.R. section 2.203(b), the EPA may make this information available to the public without further notice to Pure Maintenance of Colorado LLC.
- 91. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

- 92. The issuance of this Order shall not constitute a waiver by the 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.
- 93. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
- 94. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(1), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
- 95. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by the EPA.
- 96. If any provision of this Order is subsequently held to be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

		DAVID	Digitally signed by DAVID COBB
Date:	By:	COBB	Date: 2021.03.01 16:48:04 -07'00'
		David Cobb, Sec	etion Chief
		Toxics and Pesti	cides Enforcement Section
		Enforcement and	l Compliance Assurance Division