

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

IN THE MATTER OF:)	
)	Docket No. FIFRA-08-2024-0018
Evolution CPAP LLC)	
)	FIFRA SECTION 13(a)
)	
11739 S Digory Drive)	STOP SALE, USE, or
South Jordan, Utah 84009)	REMOVAL ORDER
)	
Respondent.)	
)	
)	
)	

I. AUTHORITY

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 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 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.

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. § 136a.
4. 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 that is misbranded.
5. 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 section 19 of FIFRA.
6. 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.”
7. 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 microorganism (except viruses, bacteria, or other

microorganisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).”

8. Pursuant to the authority in section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), the Administrator established that “an organism is declared to be a pest under circumstances that make it deleterious to man or the environment, if it 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).
9. Section 2(h) of FIFRA, 7 U.S.C. § 136(u), defines “pesticide” as “(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer....”
10. 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.”
11. 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.”
12. 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.”
13. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), provides that, among other reasons, a pesticide is misbranded if:
 - (A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false and 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 under the name of, another pesticide;
 - (D) its label does not bear the registration number assigned under section 136e of this title [FIFRA section 7] to each establishment in which it was produced;
 - (E) any word, statement, or other information required by or 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;

(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 136a(d) of this title [FIFRA section 3(d)], 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 136a(d) of this title [FIFRA section 3(d)], is adequate to protect health and the environment[.]

14. Section 2(q)(2) of FIFRA, 7 U.S.C. § 136(q)(2), provides that, among other reasons, a pesticide is misbranded if:

(C) 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 clearly be read, a label bearing—

- (i) the name and address of the producer, registrant, or other person for whom produced;
- (ii) the name, brand, or trademark under which the pesticide is sold;
- (iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; 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[.]

15. FIFRA's labeling requirements at 40 C.F.R. part 156 require that labels for pesticide products must contain several pieces of information, including the producing establishment number, hazard and precautionary statement, and directions for use. 40 C.F.R. § 156.10(a).

III. BASIS FOR THE ORDER

17. Respondent, Evolution CPAP LLC, is a limited liability company organized under the laws of the State of Utah and is therefore a "person" as that term is defined by section 2(s) of FIFRA, 7 U.S.C. § 136(s), subject to FIFRA and its implementing regulations.

18. On November 15, 2023, a representative of the EPA inspected Respondent's facility located at 1995 S 4490 W Salt Lake City, Utah 84104 (the Facility), to determine Respondent's compliance with FIFRA (the Inspection).

19. The EPA also conducted a review of Respondent's website: <https://www.sani-bot.com/>.

20. Upon review of the information collected at the Inspection and upon review of Respondent's website <https://www.sani-bot.com/>, the EPA has reason to believe Respondent has distributed or sold, and continues to distribute or sell unregistered and misbranded pesticides, specifically **Sani Bot Cleansing Tablets, Sani Bot D3, D3+Cyclone**, and the **Sani Bot D6 (Subject Products)** in violation of FIFRA.

21. During the Inspection, the EPA observed the **Sani Bot Cleansing Tablets** and the **Sani Bot D3** at Respondent's Facility being held for distribution or sale.
22. The **Sani Bot Cleansing Tablets** and the **Sani Bot D3** were also offered for sale and distribution online through Respondent's website, <https://www.sani-bot.com/order/>.
23. The EPA observed two additional products: the **Sani Bot D3+Cyclone** and **Sani Bot D6**, that were also offered for sale and distribution online through Respondent's website, <https://www.sani-bot.com/order/>.
24. The **Sani Bot Cleansing Tablets** product is a chemical tablet that is used in **Sani Bot D3**, **Sani Bot D3+Cyclone** and **Sani Bot D6**.
25. The **Sani Bot Cleansing Tablets** are included with the sale and distribution of the **Sani Bot D3**, the **D3+Cyclone**, and the **Sani Bot D6**. The **Sani Bot Cleansing Tablets** can also be purchased on their own.
26. The **Sani Bot Cleansing Tablets** labeling includes the following language:
 - "Sani Bot CPAP Mask Cleaner"
 - "Drop 1-2 tablets into your Sani Bot tank as directed in the Sani Bot user manual."
 - "<http://www.sani-bot.com>"
 - "Recommended for use with Sani Bot CPAP Mask Cleaning Machines for sanitization of CPAP Masks and Tubes."
27. The **Sani Bot D3** labeling includes the following language:
 - "Why the Sani Bot D3 CPAP Mask Cleaner is the right choice for you and your family...heater function for advanced disinfection."
 - "60 Powerful cleansing tablets (included)"
 - "Improve your health"
 - "Maintain Professional Disinfection at Home"
 - "Sani Bot D3 effectively sanitizes CPAP apparatus utilizing the cleansing power of ultrasound, water and powerful SaniTabs disinfectant tablets delivering heavy duty, medical sanitation and disinfection within the comfort of your own home."
 - "Why spend your precious time trying to clean your CPAP headgear manually, when you can simply use our patented, state-of-the-art disinfecting device to do the job for you?"
 - "Completely automated. Sani Bot CPAP cleaner sanitizes leaving breathing mask & tubes sparkling clean at the push of a button."
 - "Simply fill the stainless-steel tank with water, add a cleansing tablet, submerge your mask and tube, then set the 1–30-minute (Full range) times."
 - "Includes stainless Steel Submersion Plate to keep contents completely submersed during cleaning cycle so you can be confident that nasty bacteria, mold, and mildew will be eliminated from your CPAP accessories."

28. The website <https://sanibot.wpengine.com/product/sani-bot-d3x/> includes the following language regarding the **Sani Bot D3+Cyclone**:
- “MAINTAIN PROFESSIONAL DISINFECTION AT HOME: Sani Bot’s D3X efficient CPAP apparatus sanitizer utilizing the cleansing power of ultrasound, water and powerful SaniTabs disinfectant tablets to deliver heavy duty, medical sanitation and disinfection within the comfort of your own home.”
 - “SET IT AND FORGET IT: Why spend your precious time trying to clean your CPAP headgear manually, when you can simply use our patented, state-of-the-art disinfecting device to do the job for you?”
 - “Completely automated, Sani Bot CPAP mask cleaner sanitizes a sparkling clean breathing mask at the push of a button. Simply fill the stainless steel tank with water, add a cleansing tablet, submerge your mask, and set the 1-30 minute (full range) timer.”
 - “Equipped with a sleek, touch screen panel for simple 1-2-3 step operation, and specialized ceramic heater function for superior cleaning and advanced disinfection mode for deep cleaning up to 140.”
 - “Includes Stainless Steel Submersion Plate so you can be confident that nasty bacteria, mold and mildew will be eliminated from your CPAP access.”
29. The website <https://sanibot.wpengine.com/product/sani-bot-d6/> includes the following language regarding the **Sani Bot D6**:
- “MAINTAIN PROFESSIONAL DISINFECTION AT HOME: Sani Bot’s Patented CPAP apparatus sanitizer utilizes the cleansing power of ultrasound, water and powerful SaniTabs disinfectant tablets (60 day supply included) to deliver heavy duty, medical sanitation and disinfection within the comfort of your own home.”
 - “SET IT AND FORGET IT: Why spend your precious time trying to clean your CPAP headgear manually, when you can simply use our patented, state-of-the-art disinfecting device to do the job for you?”
 - “Completely automated, Sani Bot CPAP D6 mask cleaner sanitizes leaving breathing mask & tubes sparkling clean at the push of a button.”
 - “Includes Stainless Steel Submersion Plate to keep contents completely submersed during cleaning cycle so you can be confident that nasty bacteria, mold and mildew will be totally eliminated from your CPAP accessories.”
30. These claims for each product indicate that the **Subject Products** are substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating any pest, and thus, pesticides pursuant to section 2(h) of FIFRA, 7 U.S.C. § 136(u).
31. None of the **Subject Products** are registered with the EPA.
32. None of the **Subject Products**’ labels bear a registration number assigned under FIFRA section 7 to the establishment in which the products were produced, making them misbranded pursuant to section 2(q)(1)(D) of FIFRA, 7 U.S.C. § 136(q)(1)(D).

33. Respondent has distributed or sold, and continues to distribute or sell, the **Subject Products** in violation of section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), which prohibits the sale of unregistered pesticides.
34. Respondent has distributed or sold, and continues to distribute or sell, the **Subject Products** in violation of section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), which prohibits the sale of misbranded pesticides.

IV. ORDER

35. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), EPA hereby orders Respondent to immediately cease the sale, use, or removal of all the **Subject Products** under its ownership, control, or custody, wherever such products are located, except in accordance with the provisions of this Order.
36. The **Subject 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, for any reason, other than in accordance with the provisions of this Order and any provisions of any written modifications to this Order.
37. Should Respondent seek an exception to this Order's prohibitions, Respondent may submit a request to EPA, in accordance with the following:
 - a) Requests must be made in writing by electronic mail to Christine Tokarz, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency, at tokarz.christine@epa.gov.
 - b) Any request for movement or removal must include a written accounting of the products to be moved, including the quantity (type, number, and volume of containers) to be moved, the address of the facility from which the products will be moved, the address of the destination facility, and an explanation of the reasons for the request.
 - c) If the movement or removal is for the purposes of disposal, Respondent must provide written proof of disposal to EPA, including proof of compliance with all applicable federal, state, and local laws.
 - d) Any movement or removal of any **Subject Products** made without prior written authorization from EPA in accordance with this paragraph constitutes a violation of this Order and the distribution or sale of an unregistered and misbranded pesticide in violation of FIFRA.
38. Within 30 days of receipt of this Order, Respondent must submit to EPA a written accounting of the **Subject Products** subject to this Order. The accounting must be submitted to Christine Tokarz, at the e-mail address above, and must include the following:

- e) An accounting of all existing product inventory at any of Respondent's facilities or warehouses, including the location(s) where the products are held, quantities, and container sizes;
 - f) A list of each shipment of **Subject Products** en route to any of Respondent's establishments from any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amount held by each type of container, the name and address or addresses from which the shipment was shipped and the destination establishment(s); and
 - g) A list of each shipment of **Subject Products** en route from any of Respondent's establishments to any person on or after the date of this Order. The list shall include the quantities being shipped, including number and types of containers, and amounts held by each type of container, the establishment from which the shipment was shipped and the destination establishment(s).
39. Respondent must provide EPA with an updated accounting at least every 30 days thereafter until Respondent no longer has **Subject Products** in its ownership, custody, or control.
40. The information requested herein must be provided 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 in accordance with the regulations at 40 C.F.R. § 2.203(b) by labeling such information at the time it is submitted to EPA as "trade secret" or "proprietary" or "company confidential" or other suitable notice. Information subject to a properly made claim of business confidentiality will be disclosed by EPA to the public only in accordance with the procedures set forth at 40 C.F.R. part 2, subpart B. If Respondent does not make a proper claim at the time that it submits the information in the manner described in 40 C.F.R. § 2.203(b), EPA may make this information available to the public without further notice to Respondent.

V. OTHER MATTERS

41. Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.
42. 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.
43. This Order shall be effective immediately upon receipt by Respondent or any of Respondent's agents.
44. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.
45. This Order shall remain in effect unless and until revoked, terminated, suspended, or modified in writing by EPA.

46. 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**

Date: _____

By: _____

David Cobb, Section Supervisor
Toxics and Pesticides Enforcement Section
Enforcement and Compliance Assurance Division