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U.S. EPA REGION 8
HEARING CLERK

SENT VIA EMAIL

DELIVERY RECEIPT REQUESTED

SUBJECT: Requested action to be taken regarding the Ozone Generator Nano 15 in shipment with entry number SCS-97142305 FIFRA-08-2025-0018

FROM: David Cobb
Supervisor, Toxics Enforcement Section
Enforcement and Compliance Assurance Division

Cobb,
David
Digitally signed
by Cobb, David
Date: 2025.04.02
17:25:25 -06'00'

TO: U.S. Department of Homeland Security
Bureau of Customs and Border Protection
Pembina, North Dakota 3401

By this memorandum, the U.S. Environmental Protection Agency, Region 8, is informing the Bureau of Customs and Border Protection of the U.S. Department of Homeland Security (CBP) that the products in the import shipment described below should be **Denied Entry-Refused Delivery** pursuant to the authority of section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136o(c), and the implementing regulations at 19 C.F.R. section 12.114. The entry was marked “Hold Intact,” “Refused,” and “Re-Export” in the Automated Commercial Environment (ACE) by the EPA on April 1, 2025.

The following information pertains to the shipment:

- The importer and consignee is Anric Technologies LLC, 230 Lincoln Street, Lexington, Massachusetts, 02421-7521.
- The manufacturer is Absolute Ozone EPA Establishment Number 97808-CAN-1.
- The broker is UPS.
- The bill number is UPSCR9528AHM9L82.
- The entry file date was March 26, 2025.
- The product in this shipment is 2 Nano 15 Ozone Generators, weighing 30 pounds.
- The port of entry is Pembina, North Dakota 3401.

Section 2(t) of FIFRA, 7 U.S.C. § 136(t) defines “pest” as “(1) any insect, rodent, nematode, fungus, weed, or (2) 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.”

Section 2(h) of FIFRA, 7 U.S.C. § 136(h), defines “device” as “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.” See also 40 C.F.R § 152.500(a).

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....”

Under FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1), a device is misbranded and subject to enforcement action if, among other reasons:

- the labeling bears any statements, designs, or graphic representations that are false or misleading (see also 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3);
- it is an imitation of, or is offered for sale under the name of another device;
- the label fails to bear the establishment number of the establishment where it was produced;
- any required information is not prominently displayed on the label;
- it lacks adequate directions for use; or
- it lacks an adequate warning or caution statement.

The label on the Nano 15 Ozone Generators includes the following language:

- “EPA Establishment No: 97808-CAN-1”
- “www.absoluteozone.com”

The website, www.absoluteozone.com, includes the following language:

- “Ozone’s remarkable ability to instantly neutralize biological matter helps kill bacteria and viruses without introducing unpleasant odors or tastes, further cementing its effectiveness in water treatment and purification.”
- “The Ozone produced in the ozone generator is then dispersed into the air to eliminate odours, bacteria, and other contaminants.”
- “In a chemical reaction, Ozone oxidizes organic substances and kills hazardous germs and viruses.”
- “Effective disinfection: Ozone is a highly reactive gas that can effectively kill bacteria, viruses, and other pathogens in water.”
- “Ozonated olive oil- Did you know that ozonated olive oil has unique properties, making it a great natural remedy for various skin conditions and health issues?”

During the ozonation process, the oil changes its chemical composition, which gives it biological properties that can help fight bacteria and promote healing. Ozonated olive oil has been used to treat dermatitis, acne, pressure ulcers, and other skin diseases, and it is also effective in post-laser therapy and sunburn skincare. This amazing substance can also be used as a therapeutic agent for ailments such as asthma, gastrointestinal ulcers, and intestinal infections.”

- “Ozone Dental- Ozone, the most powerful oxidant, has a wide range of applications in dentistry. It has demonstrated its effectiveness in treating various dental problems, including tooth decay, periodontal disease, temporomandibular joint pain, and several other infections.”
- “Ozone Therapy- Ozone therapy has become widely used in numerous countries due to its diverse applications. Ozone boasts a range of benefits, including anti-inflammatory, bactericidal, antiviral, fungicidal, and analgesic properties.”
- “It is not associated with any harmful illnesses, unlike most chemical disinfectants.”
- “Increased safety: Ozone does not produce toxic disinfection by-products like chlorinated compounds, making it a safer option for drinking water treatment.”
- “Larger aquariums, zoos, and hatcheries are constantly looking for new and efficient ways of protecting different species in their facilities. One of the most effective ways of providing this safety is using ozone treatment for water disinfection.”
- “Data and experience suggest that chemical treatment of the water utilized by different animal species has many health concerns. Ozone is a cost-effective and non-invasive water treatment solution to keep animals healthy and happy.”
- “Ozone for Pharmaceutical- Ozone is the most powerful, effective, and economical disinfectant/oxidant. It has been proven to be the best choice for biopharmaceutical and pharmaceutical water systems due to its superior results. Since ozone is produced and does not leave any residue or by-products, it is considered the safest disinfectant/oxidant alternative.”
- “Commercial Ozone Swimming Pools & Parks- Ozone is the best alternative to chlorine as a disinfectant agent in swimming pools. Ozone can safely prevent the formation of dangerous chlorine by-products. In addition to being greener, healthier, and more pleasant, ozone also saves you money.”
- “Residential Ozone Swimming Pools & Spas- Ozone is a powerful oxidizer that effectively eliminates contaminants and keeps pool water clean. Its use has the added benefit of preventing the creation of hazardous by-products like chloramines, which cause eye irritation, leave a chlorine scent on the body, and pose a significant health risk. Using ozone as a treatment option is not only cost-effective, but also safer, healthier, and more agreeable compared to chemical treatments.”

These statements and the EPA establishment number listed above demonstrate a pesticidal intent pursuant to the definitions above.

Based on the information provided, the Nano 15 Ozone Generators in the shipment referenced above fall within the definition of devices under FIFRA section 2(h), 7 U.S.C. § 136(h), and 40 C.F.R § 152.500(a) as “any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest, [which includes virus, bacteria, or other micro-organism,] or any other form of plant or

animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.”

The claims listed on the website, www.absoluteozone.com, above, indicate that the product is misbranded pursuant to the following provision:

- 40 CFR 156.10(a)(5)(i), A false or misleading statement concerning the composition of the product;
- 40 C.F.R. 156.10(a)(5)(ii), A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- 40 C.F.R. 156.10(a)(5)(iii), A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- 40 C.F.R. 156.10(a)(5)(iv), A false or misleading comparison with other pesticides or devices;
- 40 C.F.R. 156.10(a)(5)(vii), 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)(x), Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
 - (A) “Contains all natural ingredients”;
 - (B) “Among the least toxic chemicals known”
 - (C) “Pollution approved”

Therefore, the Nano 15 Ozone Generators in the shipment referenced above are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because the labeling bears statements, designs, or graphic representations that are false or misleading (see also 40 CFR 156.10(a)(5)).

Accordingly, based on the information provided, importing the products in the shipment referenced above is a violation of FIFRA section 12(a)(1)(F), 7 U.S.C. § 136j(a)(1)(F), as a distribution or sale of a misbranded device.

The EPA hereby notifies CBP that this merchandise should be refused admission pursuant to the authority of FIFRA § 17(c), 7 U.S.C. § 136o(c), and the implementing regulations at 19 C.F.R. § 12.114. The importer should export this merchandise or dispose of the products under supervision of the CBP within ninety calendar days from the date of this memorandum or within such additional time as the District Director of CBP specifies. Failure to do so may result in either the destruction of the merchandise as authorized by FIFRA or in any action necessary to enforce the terms of any bond under which the shipment has been released to the consignee. Alternatively, CBP may elect to seize the products as a prohibited importation pursuant to their authorities as set out at 19 U.S.C. § 1595a(c)(2)(A).

On April 1, 2025, the EPA informed the CBP Cargo Chief in Pembina, North Dakota, that it would deny entry of this shipment. Please contact Christine Tokarz, the import

enforcement coordinator, by email at tokarz.christine@epa.gov, if you have any questions concerning this matter.