

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

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Received by EPA Region VIII Hearing Clerk

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SENT VIA ELECTRONIC MAIL DELIVERY RECEIPT REQUESTED

From: David Cobb

Supervisor, Toxics Enforcement Section

Enforcement and Compliance Assurance Division

To: U.S. Department of Homeland Security

Bureau of Customs and Border Protection

Pembina, North Dakota 3401

Subject: Requested action to be taken regarding the Energen Ozone Generator Unit FIFRA-08-2023-0031

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 that the products in the import shipment described below should be **Denied Entry-Refused Delivery** into the United States pursuant to the authority of section 17(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 1360(c), and the implementing regulations at 19 C.F.R. section 12.114. The shipment was inspected by EPA Officers at the Pembina, North Dakota Port of Entry on April 13, 2023, and was determined to be out of compliance.

The following information pertains to the shipment:

- The shipper is Rhovel Dee, 171 Bitterfield Drive, Winnipeg, Manitoba R2P 1S8.
- Delivery to Returns Department Amazon Returns, 3837 Bay Lake Trail, Suite 113, Las Vegas, Nevada 89030.
- The broker is UPS, 222 South 5th Street, Pembina, North Dakota 58271.
- The outbound Airway Bill Number is LDLBUS024895446.
- The bill number is SFA12591334784-UFL00024846.
- The entry file date was April 13, 2023.
- The quantity is 1 Energen Ozone Generator unit, weighing approximately 15 pounds.
- The port of entry is Pembina, North Dakota 3401.
- The country of origin is Canada.

Section 12(a)(1)(F) of FIFRA, 7 U.S.C. 136j(a)(1)(F), provides that it shall be unlawful for any person in any State to distribute or sell to any person any device which is misbranded.

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(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 microorganism (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(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 40 CFR 156.10(a)(5) below);

40 C.F.R. § 156.10(a)(5) provides that a pesticide or a device 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 false or misleading statement concerning the effectiveness of the product as a pesticide or device. 40 C.F.R. § 156.10(a)(5)(ii).
- A false or misleading comparison with other pesticides or devices. 40 C.F.R. § 156.10(a)(5)(iv).
- 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).
- 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).
- Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed". 40 C.F.R. § 156.10(a)(5)(ix).

The product label for these units has the following language:

- "Ozone Sanitation in Progress"
- "www.oionair.com"

Claims made for the product are also found on the website, www.oionair.com:

• "Enerzen 0-777 – 11,000 mg/h Industrial Ozone Generator -O3 Air Purifier Deodorizer Ionizer **Sterilizer**"

The Energen Ozone Generator units are labeled with the EPA Establishment Number 94263-CHN-1, contained directions for use, and a caution or warning statements on their label.

These Energen Ozone Generator units are devices under FIFRA section 2(h), 7 U.S.C. § 136(h), and 40 C.F.R § 152.500(a) because they fall within the definition of "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."

These devices make the following false or misleading statements: "Sterilizer." Therefore, these products are misbranded pursuant to 7 U.S.C. § 136(q)(1). Importing these 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 shipment that arrived at the border for import is also in violation of FIFRA section 12(a)(2)(N), 7 U.S.C. § 136j(a)(2)(N), because a registrant, wholesaler, dealer, retailer, or other distributor failed to correctly file reports required by the Act. As required by 19 C.F.R. § 12.114, a Notice of Arrival of Pesticides and Devices (NOA), EPA form 3540-1, and a copy of one product label must be submitted. Therefore, the shipment that arrived at the border was also in violation of FIFRA section 12(a)(2)(N), 7 U.S.C. § 136j(a)(2)(N).

The Agency hereby notifies U.S. Customs and Border Protection that this merchandise has been refused admission and recommends that this merchandise be re-exported or destroyed within 90 calendar days from the date of this Notice.

On April 13, 2023, the Customs and Border Patrol Cargo Team in Pembina, North Dakota was informed by the EPA that it would deny entry of this shipment.

Please contact Christine Tokarz, the import enforcement coordinator, by phone at (303) 312-6147 or by email at tokarz.christine@epa.gov if you have any questions concerning this matter.