



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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Hearing Clerk

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SENT VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

From: David Cobb
Section Chief, Toxics Enforcement Unit
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 ExOzone ® EX-SR-100 devices in shipment with entry number M50-08236882 FIFRA-08-2022-0006

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. § 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 ACE by the EPA on October 15, 2021.

The following information pertains to the shipment:

- The importer and consignee is Ozone Partner, 5313 Serene Hills Drive, Auston, Texas 78738-1248.
- The manufacturer is Ozone Partner Inc, 1604 290 Newport Drive, Port Moody, British Columbia V3N 5N2 Canada.
- The broker is Northern Customs Services, Inc, point of contact, William Sherman, wsherman@northerncustoms.com.
- The bill number is DAYRVAN3637188.
- The entry file date was October 9, 2021.
- The quantity is 6 ExOzone ® EX-SR-100 devices.
- The port of entry is Pembina, North Dakota 3401.
- The country of origin as entered in ACE is Hungary.

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(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(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....”

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)).

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);
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3) (as of 2010, such standards have yet to be established for devices);
- 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 ExOzone ® EX-SR-100 User Manual has the following statements about the device, “Intended use and other information- The equipment can be used to disinfect objects and surfaces in premises, air spaces of rooms, observing the ambient thresholds of proper operation.”

These ExOzone ® EX-SR-100 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.”

The ExOzone ® EX-SR-100 devices are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there are no directions for use, and no caution or warning statements on their label or labelling. The EPA Establishment Number listed on the label, 93758-HUN-01 is not in compliance with FIFRA regulations.

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 file reports required by the Act. As required by 19 C.F.R. section 12.114, a Notice of Arrival of Pesticides and Devices, EPA form 3540-1, and a copy of one product label must be submitted.

Therefore, none of the products referenced above in the shipment with entry number M50-08236882 can be allowed entry into the United States.

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 October 15, 2021, the Customs and Border Patrol unit chief 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.