



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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DELIVERY RECEIPT REQUESTED

From: David Cobb
Section Supervisor, Toxics & Pesticides 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 Clear Blue Mineral Ionizer and the Ultrazo3ne™ Ozone Sanitation System in shipment with entry number DN2-2188245-4

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 entries was marked “Hold Intact,” “Refused,” and “Re-Export” in ACE by the EPA on August 30, 2023.

The following information pertains to the shipment:

- The importer is Northern Lights Cedar Tubs Inc., 835 Kapelus Drive, West Saint Paul Manitoba R4A5A4 Canada. Point of contact, BRIAN@CEDARTUBS.COM.
- The consignee is Balcom Investment Solutions, 2270 Carillon Point, Kirkland, Washington 98033-7446.
- The broker is GHY USA, Inc. Points of contact, Team Discovery teamdiscovery@ghy.com, Leslie Brooker LeslieB@ghy.com.
- The bill number is A BFS371194073.
- The entry file date was August 28, 2023.
- The quantities are:
 - 1 Clear Blue Mineral Ionizer, weighing 5 pounds.
 - 1 Ultrazo3ne™ Ozone Sanitation System, weighing 5 pounds.
- The port of entry is Pembina, North Dakota 3401.
- The country of origin as entered in ACE is Canada.

The shipment that arrived at the border for import is in violation of FIFRA section 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), which states that it is unlawful for any person to distribute or sell any

pesticide that is not registered under section 3 of FIFRA, 7 U.S.C. § 136a. Under FIFRA, a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. Section 2(u) of FIFRA, 7 U.S.C. § 136(u). (See also 40 C.F.R. § 152.15.)

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 also 40 CFR 156.10(a)(5));
- 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.

Clear Blue Mineral Ionizer is an EPA registered product, EPA Reg. No. 90859-2.

The manufacturer’s website for the product, Ultrazo3ne™ Ozone Sanitation System <https://www.balboawater.com/Ultrazo3ne>, provided by the consignee on August 23, 2023, has the following language:

- “Disinfect your water naturally”
- “Ultrazo3ne™ produces powerful oxidant”
- “Ultrazo3ne™ disinfects water by killing viruses and biological contaminants”

These Ultrazo3ne™ Ozone Sanitation System 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 Ultra3ne™ Ozone Sanitation Systems are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there is no EPA Establishment Number, no directions for use, and no caution or warning statements on their label or labelling. 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.

- The ACE entry data for the Clear Blue Mineral Ionizer did not include an EPA registration number, nor an uploaded copy of the on-product label.
- There was no data for the Ultra3ne™ Ozone Sanitation System in ACE.

Therefore, none of the products referenced above in the shipment with entry number DN2-2188245-4 should 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 August 30, 2023, 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.