UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8
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SENT VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

From: David Cobb
Chief, Toxics Enforcement Section
Enforcement and Compliance Assurance Division

DAVID COBB Digitally signed by DAVID COBB Date: 2022.02.15 16:29:57 -07'00'

To: U.S. Department of Homeland Security
Bureau of Customs and Border Protection
Denver, Colorado 3307

Subject: Requested action to be taken regarding the Akai Ultraviolet System Activated Ionizing Water, MS-900 UV units, the KA-P930T Filter Cartridges, the KA-P805 Filter Cartridges, and the UV Lamps in shipment with entry number 336-31345399
FIFRA-08-2022-0025

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 February 11, 2022.

The following information pertains to the shipment:

- The importer and consignee is High Tech Health International, 5621 Arapahoe Avenue #D, Boulder, Colorado 80303.
- The broker is DHL Global Forwarding, Sarah Mclellan, Sarah.Mclellan@dhl.com.
- The bill number is ONEYSINBA0991300.
- The entry file date was January 27, 2022.
- The quantities are:
    - 42 - Akai Ultraviolet System Activated Ionizing Water Equipment, MS-900 UV units
    - 10 - KA-P930T Filter Cartridges
    - 30 - KA-P805 Filter Cartridges
    - 100 - UV Lamps
- The port of entry is Denver, Colorado 3307.
- The country of origin as entered in ACE is Japan.

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.

In accordance with 40 C.F.R. § 156.10(a)(5), 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:

- "Water electrolyzer"
- "For service and replacement filters: High Tech Health International Inc. USA and Canada: 1-800-794-5355… www.hightechhealth.com"

The "Akai MS-900UVH/HD Operators Manual" that accompanies the product includes the following claims:

- "Mode indicators…purified water"
- "There are two types of filter cartridges that can be used with this unit. 1. KA-P900T…eliminates unwanted odors such as chlorine odor, mold odor, metallic odor, etc.. Also eliminates rust, muddiness, mold, and various bacteria through the use of hollow fiber membranes."
- "Purified water can be used for taking medicine"
- "For increased safety, the water generated by the unit irradiated with electromagnetic waves produced by the ultra violet lamp. The length of this electromagnetic wave is 253.7nm, which is an effective length for sterilizing drinking water."

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

- "Upgrade Your Water: The Ionizer Plus® water ionizer transforms your tap water into the healthiest water possible. By alkalinizing your water and concentrating the minerals already present in your water and making them and the water itself more easily absorbed by the body, Ionizer Plus water has the capability to reverse metabolic acidosis, and promote the increased excretion of toxins. It also has all the filtration and purification that you will ever need – all in one modest counter-top unit."
- "Membrane Filter - Removes All Bacteria"
- "Ultraviolet Disinfection for Viruses"
- "Filtration: The water routed through the ionizer first encounters the granular activated carbon portion of the filter where chlorine and chemicals are absorbed. Next it goes through a hollow-fiber membrane. This state-of-the-art filter removes everything larger than .1 micron (one tenth of a micron), which includes all bacteria. This feature will eliminate such bacteria as e.Coli, giardia, and crypto sporidium."

These Akai Ultraviolet System Activated Ionizing Water, MS-900 UV units, the KA-P930T Filter Cartridges, the KA-P805 Filter Cartridges, and the UV Lamps 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 the Akai Ultraviolet System Activated Ionizing Water, MS-900 UV units, the KA-P930T Filter Cartridges, the KA-P805 Filter Cartridges, and the UV Lamps 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 labels.

These Akai Ultraviolet System Activated Ionizing Water, MS-900 UV units, the KA-P930T Filter Cartridges, the KA-P805 Filter Cartridges, and the UV Lamps are also misbranded because the labeling is false or misleading as defined by 7 U.S.C. § 136(q)(1) and 40 C.F.R. § 156.10(a)(5).

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 336-31345399 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 February 11, 2022, the Customs and Border Patrol unit chief in Denver, Colorado, 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.