

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 8

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SENT BY 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 Salt Lake City, Utah, 3303
- Subject: Requested action to be taken regarding the HydroBlu products in shipment with entry number 274-02683190 FIFRA-08-2021-0054

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 entry was marked "Hold Intact," "Refused," and "Re-Export" in ACE by the EPA on April 28, 2021.

The following information pertains to the shipment:

- The importer is Kaybe Health Science LLC, 3653 W 1987 S, Salt Lake City, Utah 84104-4904.
- The consignee is Hydro Health LLC, 3653 W 1987 S, Salt Lake City, Utah 84104-4904.
- The manufacturer is Xiamen Vork Health Industry Co Ltd, 16, Xianghong Road, Xiang'an District, Xiamen, 361101, China.
- The broker is TOH International, point of contact John Tracy, jtracy@tohint.com.
- The bill number is COSU6295804670.
- The entry file date was May 5, 2021.
- The quantities are:
 - 1,200 HydroBlu Sidekick 3-Stage Straw Water Filter (SKU HB-SF-01)
 - 0 1,500 HydroBlu Versa Flow Inline Water Filter (SKU IIB-VF-01)
 - 1,500 HydroBlu Versa Flow Water Filter Package (SKU HB-VF-02)
 - 500 HydroBlu Virus UF Hollow Fiber Filter Module 0.02UM (SKU IIB-VUF-01)
- Total weight of these devices is 790 pounds,

- The port of entry is Salt Lake City, Utah 3303.
- The country of origin as entered in ACE is China.
- Each of the four devices is labeled with an EPA Establishment Number of 94660-CHN-01 and the website, <u>https://hydroblu.com/</u>.

Section 12(a)(1)(F) of FIFRA, 7 U.S.C. 136j(a)(1)(F) and 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 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...."

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 shipment of the HydroBlu Sidekick 3-Stage Straw Water Filter (SKU HB-SF-01) <u>https://hydroblu.com/sidekick-3-stage-straw-water-filter/</u> products that arrived at the border for import has labeling with the following language:

- "The easy to use Sidekick protects you from bacteria, chemicals, heavy metals, and other contaminates."
- "Removes bacteria, such as Giardia, E coli, cryptosporidium, and more."

The shipment of the HydroBlu Versa Flow Inline Water Filter (SKU IIB-VF-01), <u>https://hydroblu.com/versa-flow-light-weight-water-filter/</u> products that arrived at the border for import has labeling with the following language:

- "Meaning the hollow fiber tubes have thousands of tiny holes (0.1 microns) that block 99.9999% of harmful bacteria, Giardia, E. coli, protozoan cysts, Cryptosporidium and more."
- "Removes: Bacteria, Protozoan cysts, Giardia, Cryptosporidium, E. Coli, Salmonella and more"

The shipment of the HydroBlu Versa Flow Water Filter Package (SKU HB-VF-02), <u>https://hydroblu.com/versa-flow-light-weight-water-filter-package/</u> products that arrived at the border for import has labeling with the following language:

• "The hollow fiber has thousands of tiny holes (0.1 microns) that block 99.9999% of harmful bacteria, Giardia, E. coli, protozoan cysts, Cryptosporidium, and more."

The shipment of the HydroBlu Virus UF Hollow Fiber Filter Module 0.02UM (SKU IIB-VUF-01), <u>https://hydroblu.com/virus-ultrafiltration-hollow-fiber-replacement-filter/</u> products that arrived at the border for import has labeling with the following language:

- "Removes viruses such as Hepatitis A, Polio, Typhoid, Enteroviruses and more."
- "Removes bacteria, Giardia, E. Coli, Cryptosporidium, Cholera, Protozoa Cysts, Parasites, and more"

These HydroBlu products 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 HydroBlu products' labels are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there is no caution or warning statements on their label or labelling. The HydroBlu products are also misbranded because the labeling is false or misleading in multiple particulars, 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. The entry information indicated that there was one pesticide device being imported, however there were four.

Therefore, none of the products referenced above in the shipment with entry number 274-02683190 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 June 2, 2021, the Customs and Border Patrol unit chief in Salt Lake City, Utah, 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.