



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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7/31/2023

8:32 AM

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Ref: 8ENF-AT-P

SENT VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

From: David Cobb
Section 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 LeveLuk K8 Kangen Water Filter in shipment described below FIFRA-08-2023-0062

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. § 12.114. CBP Officers in Pembina North Dakota inspected this product upon attempted import and coordinated with EPA to determine it was out of compliance on July 17, 2023.

The following information pertains to this shipment:

- Air Waybill No./ Tracking No./ Bill of Lading: 77272436610/ 772724366030
772724366625
- Exporter: Kim Vo, voll@telus.net, 3224 56 Street NE, Calgary Alberta T1 Y2E9, Canada
- Consignee: Tam Vy Tran, 1891 Binnies Way, Buford, Georgia, 30519-8219
- Quantity: 3 units, weighing 66 pounds

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));
- 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 LeveLuk K8 Kangen Water Filter is accompanied by an “Info Sheet” that includes the following language:

- “To be used as a disinfectant”
- “It also destroys pathogenic bacteria on fruit”

These claims demonstrate a pesticidal intent pursuant to the definitions above. The LeveLuk K8 Kangen Water Filter is thus a pesticide device and subject to FIFRA regulation.

The LeveLuk K8 Kangen Water Filter is a device under FIFRA section 2(h), 7 U.S.C. § 136(h), and 40 C.F.R § 152.500(a) because it falls 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 LeveLuk K8 Kangen Water Filter is 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.

Therefore, this product is misbranded pursuant to 7 U.S.C. § 136(q)(1). Importing the product 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, none of the product referenced above can be allowed entry into the United States.

On July 18, 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.