



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 8

1595 Wynkoop Street  
Denver, CO 80202-1129  
Phone 800-227-8917  
www.epa.gov/region8

8/18/2023

12:58 PM

Received by  
EPA Region VIII  
Hearing Clerk

Ref: 8ENF-AT-P

**SENT VIA ELECTRONIC MAIL**  
**DELIVERY RECEIPT REQUESTED**

From: David Cobb  
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-08-2023-0064

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 August 17, 2023.

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.

40 CFR 156.10(a)(5) states: Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 152.500, 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:

- (i) A false or misleading statement concerning the composition of the product;
- (ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- (iv) A false or misleading comparison with other pesticides or devices;
- (v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;
- (vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;
- (vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;
- (viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;
- (ix) 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”; and
- (x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:
  - (A) “Contains all natural ingredients”;
  - (B) “Among the least toxic chemicals known”
  - (C) “Pollution approved”

The LeveLuk K8 Kangen Water Filter is accompanied by an “Info Sheet” that has the following language:

- “Strong acidic water has excellent cleansing power. Use it to wash kitchen utensils, countertops and more.”
- “Reduce bacteria”
- “To sterilize vegetables”

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.

The LeveLuk K8 Kangen Water Filter is also misbranded because the labeling contains false or misleading statements including, “to sterilize vegetables” as defined by 7 U.S.C. § 136(q)(1) and 40 C.F.R. § 156.10(a)(5).

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 August 17, 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](mailto:tokarz.christine@epa.gov) if you have any questions concerning this matter.