

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION 8

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SENT VIA ELECTRONIC MAIL DELIVERY RECEIPT REQUESTED

From: David Cobb

Supervisor, Toxics and Pesticides Enforcement Section Enforcement and Compliance Assurance Division

To: U.S. Department of Homeland Security

Bureau of Customs and Border Protection

Sweetgrass, Montana 3310

Subject: Requested action to be taken regarding the Precision Design & Manufacturing Inc PWS

BFDSA-2 Water Dispensing Units in the shipment with entry number 551-11565021 FIFRA-08-2023-0051

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 Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Units 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, 7 U.S.C.

§ 136o(c), and the implementing regulations at 19 C.F.R. § 12.114. The shipment was inspected by EPA Officers on May 18, 2023, and determined to be out of compliance. This entry was marked "Hold Intact," "Refused," and "Re-Export" in ACE by the EPA on May 24, 2023.

The following information pertains to the shipment of the Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Units:

- The importer is Precision Design & Manufacturing, 9024 100 Street, Westlock Alberta, T7P2L4 Canada.
- The consignee is Water Specialties Inc. 4118 S 500 W Murray, Utah 84123-7801.
- The broker is A.N. Deringer, Inc., point of contact, Kristin Salem ksalem@anderinger.com.
- The file date was May 9, 2023.
- The bill number is ODFL20200329488.
- The quantity is 2 Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Units, weighing 459 pounds.
- The port of entry is Sweetgrass, Montana 3310.
- The country of origin is Canada.

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 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.

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 Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Units has the following language on its label:

- "EPA Est# 101417-CAN-1"
- "Directions for Use -See Manual Inside"
- "Caution"
- "Viqua"
- "UV Lamps: S150RL-HO"
- "www.viqua.com"

These claims demonstrate a pesticidal intent pursuant to the definitions above. The Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Unit is thus a pesticide device and subject to FIFRA regulation.

The website www.trojantechnologies.com/en/support/treatment-claims?origin=dropdown&c1=resources&c2=support&c3=treatment-claims&clickedon=treatment-claims, which has the following language:

- "The SQ-PA, S1Q-PA, S2Q Series, S5Q Series, S8Q Series, S12Q-PA, SCS-320, SC-320, SC410, VT1, VT1-DWS, VT4, VT4-DWS12, VT4-DWS, UV-1, UV-4, UVS-3, UVS-30, NX1518, PUV-7, PUV-14, STERIS, VL200, VL410, VL410M, E4-50+, F4-50+, H, H+, K, K, SHF-140, SHF-180, SHFM-290, SHFM-140, SHFM-180, SHFM-290, VH150, VH200, VH200-F10, VH410, VH410M, VH410-F20, VP600, VP600M, VP950, and VP950M UV systems inactivates Cryptosporidium, Giardia, Escherichia coli (E. coli) and fecal coliform."
- "The SV5Q-PA, SV8Q-PA, D4-V, E4-V, F4-V and plus models, PUV-8, PUV-16, VH200-V, VH410-V, and VH410M-V UV systems inactivates heterotrophs, Escherichia coli (E. coli) and fecal coliform."
- "The S2Q-OZ, S2Q-OZ/2, S8Q-OZ, and S8Q-OZ/2 inactivates Escherichia coli (E. coli), Cryptosporidium, and Giardia."
- "The D4, E4, F4, D4 Premium and Plus Models, IHS10-D4, IHS12-D4, IHS22-D4, IHS22-E4, IHS-10, UV-10, IHS12E-D4 UV systems have been validated through microbial testing. Through this testing, performance data has been generated for UV dose delivery to inactivate Cryptosporidium, Giardia, Escherichia coli (E. coli) and fecal coliform."

- "The PRO10, PRO20, SPV-1.5, SPV-15 and PRO30 UV systems inactivate Escherichia coli (E. coli), fecal coliform, Cryptosporidium, Giardia, and Rotavirus."
- "The PRO24-100 and PRO24-186 are validated through microbial testing. Through this testing, performance data has been generated for UV dose delivery to inactivate Cryptosporidium, Giardia, and Adenovirus."

The claims related to inactivation of pests are considered pesticidal claims against public health microorganisms and is considered a sterilization claim.

The Precision Design & Manufacturing Inc PWS BFDSA-2 Water Dispensing Units are misbranded because the labeling contains false or misleading statements 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.

Therefore, none of the product referenced above can be allowed entry into the United States.

On May 24, 2023, the Customs and Border Patrol unit chief in Sweetgrass, Montana, 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.