



REGION 8  
DENVER, CO 80202

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U.S. EPA REGION 8  
HEARING CLERK

SENT VIA EMAIL

DELIVERY RECEIPT REQUESTED

**SUBJECT:** Requested action to be taken regarding the SRO150 Series product in shipment with entry number E5L-24042831 FIFRA-08-2025-0060

**FROM:** David Cobb  
Supervisor, Toxics Enforcement Section  
Enforcement and Compliance Assurance Division

DAVID  
COBB

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by DAVID COBB  
Date: 2025.07.07  
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**TO:** U.S. Department of Homeland Security  
Bureau of Customs and Border Protection  
Pembina, North Dakota 3401

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 (CBP) that the products in the import shipment described below should be **Denied Entry-Refused Delivery** 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 the Automated Commercial Environment (ACE) by the EPA on July 7, 2025.

The following information pertains to the shipment:

- The importer and consignee is Tuttnauer USA Company. LTD 345 Oser Avenue, Hauppauge, New York 11788-36075.
- The manufacturer is Barik Medical Inc., 239 Cree Road, Winnipeg, R3J 3Y2 Manitoba.
- The broker is CN Customs Brokerage Services, point of contact, Jonathan Khoury [Jonathan.Khoury@cn.ca](mailto:Jonathan.Khoury@cn.ca).
- The bill of lading number: FXFC7356845790.
- The entry file date was May 29, 2025.
- The product in this shipment is 1 SRO150 Series product, weighing 200 pounds.
- The port of entry is Pembina, North Dakota 3401.

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(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).

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....”

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 also 40 CFR 156.10(a)(5));
- its packaging or wrapping does not conform to standards established pursuant to FIFRA section 25(c)(3);
- 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 labeling on the SRO150 Series product has the following language:

- “www.amerewater.com.”
- “Reverse Osmosis System for Clinical Applications.”
- “System produces 150 GPD and is ideal for: - Dental Clinics - Veterinary Clinics - Physician Offices - Clinical Chemistry Labs.”
- “The AmeriWater SRO150 Series is a complete water treatment system designed to provide low conductivity water for the final rinse and disinfection cycle of tabletop washers, freestanding washers and under counter washers.”

These statements demonstrate a pesticidal intent pursuant to the definitions above.

Based on the information provided, the SRO150 Series product in the shipment referenced above falls within the definition of a device under FIFRA section 2(h), 7 U.S.C. § 136(h), and 40 C.F.R§ 152.500(a).

The SRO150 Series product in the shipment referenced above is misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because the labeling fails to bear the establishment number of the establishment where it was produced.

Accordingly, based on the information provided, importing the 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 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, these pesticide products in the shipment referenced above should not be allowed entry into the United States.

The EPA hereby notifies CBP that this merchandise should be refused admission pursuant to the authority of FIFRA § 17(c), 7 U.S.C. § 136o(c), and the implementing regulations at 19 C.F.R. § 12.114. The importer should export this merchandise or dispose of the products under supervision of the CBP within ninety calendar days from the date of this memorandum or within such additional time as the District Director of CBP specifies. Failure to do so may result in either the destruction of the merchandise as authorized by FIFRA or in any action necessary to enforce the terms of any bond under which the shipment has been released to the consignee. Alternatively, CBP may elect to seize the products as a prohibited importation pursuant to their authorities as set out at 19 U.S.C. § 1595a(c)(2)(A).

On July 7, 2025, the EPA informed the CBP Cargo Chief in Pembina, North Dakota, that it would deny entry of this shipment. Please contact Christine Tokarz, the import enforcement coordinator, by email at [tokarz.christine@epa.gov](mailto:tokarz.christine@epa.gov), if you have any questions concerning this matter.