



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8**

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

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
Salt Lake City, Utah 3303

Subject: Requested action to be taken regarding the Ultrafiltration Membrane Modules NEOPHIL UF120-S2F units in shipment with entry number 101-77893831

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. section 12.114. The entry was marked “Hold Intact,” “Refused,” and “Re-Export” in ACE by the EPA on June 8, 2022.

The following information pertains to the shipment:

- The importer and consignee is Clean Membranes Inc. 400 W Cummings Park, Woburn, Massachusetts 01801-6576.
- The manufacturer is Polymem S.A., 3Rue De Industrie, Castanet-Tolosan, France.
- The broker is Kuehne + Nagel Inc. Point of contact, Natalie Prosser, Natalie.Prosser@kuehne-nagel.com.
- The bill number is 07450707613-22TLS01529.
- The entry file date was June 6, 2022.
- The quantity is 8 Ultrafiltration Membrane Modules NEOPHIL UF120-S2F.
- The port of entry is Salt Lake City, Utah 3303.
- The country of origin as entered in ACE is France.

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.

The marketing literature that accompanies the Ultrafiltration Membrane Modules NEOPHIL UF120-S2F units has the following claims:

- “The most compact Ultrafiltration module available on the market for the largest plants.”
- “Polymem ultrafiltration (UF) technology is the best pretreatment before demineralization or desalination : coupling Polymem UF and reverse osmosis (RO) offers a double barrier against bacteria and viruses, allows the RO system to work at a lower pressure with a reduced number of membranes and allows a lower frequency of RO membranes cleaning and replacement.”
- “Polymem UF membranes eliminates all suspended solids and microbiology to provide a high quality non-demineralised water for reuse, rejection to natural environment or post demineralisation.”

The website that was submitted for EPA review as the “Intended Use Statement” for the Ultrafiltration Membrane Modules NEOPHIL UF120-S2F units, <https://www.polymem.fr/en/applications-2/> has the following claims:

- “Polymem ultrafiltration clarifies and disinfects water in one step.”

- “Particles, pollen, parasites, algae, bacteria and even viruses are eliminated. Large organic pollutants and a large part of the mineral colloids are eliminated. The mineral salts useful to the body are preserved.”
- “Turbidity <0.2 NTU 100% of the time – Elimination of 99.9999% of microorganisms – Removal of 99.99% of viruses – Production and quality guaranteed – Modules NSF and ACS approved.”

These Ultrafiltration Membrane Modules NEOPHIL UF120-S2F 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 Ultrafiltration Membrane Modules NEOPHIL UF120-S2F are misbranded pursuant to FIFRA section 2(q)(1), 7 U.S.C. § 136(q)(1) because there is no EPA Establishment Number, there are no directions for use, and no caution or warning statements on their label.

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 correctly 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.

Therefore, none of the products referenced above in the shipment with entry number 101-77893831 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 8, 2022, 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.