



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

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

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SENT VIA ELECTRONIC MAIL
DELIVERY RECEIPT REQUESTED

From: David Cobb
Section Supervisor, Toxics and Pesticides 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 Diosol-19 in shipment with entry number EI5-16214605

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 Diosol-19 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. section 12.114. The entry was marked "Hold Intact," "Refused," and "Re-Export" in the Automated Commercial Environment (ACE) by the EPA on November 2, 2022.

The following information pertains to the shipment of the Diosol-19:

- The consignee and importer is Ottobock Healthcare LP, 11809 Domain Boulevard, Suite 400, Austin, Texas 78758-3433. Point of contact, MARK.MARTIN@OTTOBOCK.COM.
- The broker is Farrow U.S., point of contact, Shannon.Posner@Farrow.com.
- The release date was October 27, 2022.
- The bill number is 02097803156-X359958.
- The quantity is 11 pounds.
- The port of entry is Salt Lake City, Utah 3303.
- The country of origin is Germany.

The shipment that arrived at the border for import was in violation of FIFRA section 12(a)(1)(A) (7 U.S.C. § 136j(a)(1)(A)), which states that it is unlawful for any person to distribute or sell any pesticide that is not registered under section 3 of FIFRA (7 U.S.C. § 136a).

Under FIFRA, a pesticide is any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest or use as a plant regulator, defoliant, or desiccant. (7 U.S.C. § 136u). 40 C.F.R. § 152.15 states: "A substance is

considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if... [t]he person who distributes or sells the substance claims, states, or implies (by labelling or otherwise) ... [t]hat the substance... can or should be used as a pesticide.”

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....”

The label sent to the EPA regarding the importation is in German.

The importers also sent a PDF with a product description and a website link. That product description for Diosol-19 includes the following claims:

- “Diosol-19 is a ready-to-use biocompatible surface disinfectant based on hydrogen peroxide (19% H₂O₂) and silver ions (approx. 95 ppm)
- “SURFACE DISINFECTANT”
- “H₂O₂ WITH SILVER”
- “ROOM DISINFECTION”
- “Keywords: fight corona virus, corona virus on surfaces, corona virus disinfection, corona virus infection, fight coronavirus, coronavirus disinfectant, coronavirus infection ship, coronavirus lifespan surfaces”

This product description may be found at: <https://disinfection-shop.com/shop/desinfektion/flaechendesinfektionsmittel/diosol-wasserstoffperoxid-19/>.

Diosol-19 is also described online on the website, <https://room-disinfection.com/surface-disinfectant-diosol-19/>, which includes has the following language:

- “The anti-microbial effect of surface disinfectant Diosol-19 is focused on any kind of virus such as adenovirus, influenza virus, norovirus, poliovirus and rotavirus as well as spores.”
- “Primary application purpose of Diosol-19 is the so called aerosol disinfection (room disinfection or cold fogging) in combination with the DiosolGenerator models for aerosolized Hydrogen Peroxide (aHP) disinfection method”

In ACE, the product’s cargo description was listed as “cleaning disinfectant”.

These claims demonstrate a pesticidal intent pursuant to the definitions above. Diosol-19 is thus a pesticide subject to FIFRA regulation.

Diosol-19 is not registered pursuant to section 3 of FIFRA (7 U.S.C. § 136a). Therefore, Diosol-19 is an unregistered pesticide. Importing Diosol-19 in the shipment referenced above is a violation of

FIFRA section 12(a)(1)(A), 7 U.S.C. § 136j(a)(1)(A), as a distribution or sale of an unregistered pesticide.

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.

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 November 2, 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.