



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

NOV - 4 2019

REPLY TO THE ATTENTION OF

VIA EMAIL

Mr. Brandon Neuschafer
Bryan Cave Leighton Paisner LLP
One Metropolitan Square, 211 North Broadway, Suite 3600
St. Louis, MO 63102

bwneuschafer@bclplaw.com

Consent Agreement and Final Order
In the Matter of Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping
USA Inc., Docket Number FIFRA-05-2020-0001

Mr. Neuschafer:

Enclosed please find a copy of a fully executed Consent Agreement and Final Order in resolution of the above case. This document was filed on November 4, 2019 with the Regional Hearing Clerk.

The civil penalty in the amount of \$34,323 is to be paid in the manner described in paragraph 46. Please be certain that the docket number is written on both the transmittal letter and on the check. Payment is due within 30 calendar days of the filing date.

Thank you for your cooperation in resolving this matter.

Sincerely,

A handwritten signature in black ink, appearing to read "Claudia Niess".

Claudia Niess
Pesticides and Toxics Compliance Section

Enclosure

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)	Docket No. FIFRA-05-2020-0001
)	
Viscor Inc.)	Proceeding to Assess a Civil Penalty
Weston, Ontario)	Under Section 14(a) of the
)	Insecticide, Fungicide, and
in care of its US Agent,)	Rodenticide Act, 7 U.S.C. § 136l(a)
)	
M.O.T. Intermodal Shipping USA, Inc.)	
Rochester, New York)	
)	
Respondent.)	
<hr/>		



Consent Agreement and Final Order
Preliminary Statement

1. This is an administrative action commenced and concluded under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l(a), and Sections 22.13(b) and 22.18(b)(2) and (3) of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (Consolidated Rules) as codified at 40 C.F.R. Part 22.

2. The Complainant is the Director of the Enforcement & Compliance Assurance Division, U.S. Environmental Protection Agency (EPA), Region 5.

3. Respondent is Viscor Inc. (Viscor), a corporation doing business at 35 Oak Street, Weston Ontario, M9N 1A1 Canada in care of its U.S. Agent M.O.T. Intermodal Shipping USA Inc., located in Rochester, New York.

4. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

5. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

6. Respondent consents to the assessment of the civil penalty specified in this CAFO, and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

7. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

8. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

9. Respondent certifies to the best of its knowledge that it is complying with FIFRA, 7 U.S.C. §§ 136 to 136y.

Statutory and Regulatory Background

10. The importation of pesticides into the United States is governed by Sections 17(c) and (e) of FIFRA, 7 U.S.C. §§ 136o(c) and 136o(e), and the regulations promulgated thereunder by the Secretary of the Treasury in consultation with the Administrator of EPA. These regulations are found at 19 C.F.R. Part 12.110 *et seq.* See also 19 C.F.R. § 12.1(b).

11. 19 C.F.R. § 12.111 states, in pertinent part, that imported devices must not bear any statement, design, or graphic representation that is false or misleading in any particular.

12. 19 C.F.R. § 12.112(a) states, in pertinent part, that an importer desiring to import devices into the United States shall submit to the EPA, prior to the arrival of the shipment in the United States, a Notice of Arrival of Pesticides or Devices (NOA) on U.S. EPA Form 3540-1.

13. 19 C.F.R. § 141.18 states, in pertinent part, that a nonresident corporation may not enter merchandise into the United States for consumption unless it has a resident agent authorized to accept service of process against the nonresident corporation.

14. The term “importer” is defined at 19 C.F.R. § 101.1 as the person primarily liable for the payment of any duties on the merchandise, or an authorized agent acting on his behalf.

The importer may be the importer of record.

15. Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), states that it shall be unlawful for any person in any State to distribute or sell to any person any device which is misbranded.

16. Section 12(a)(2)(N) of FIFRA, 7 U.S.C. § 136j(a)(2)(N), states that it shall be unlawful for any person who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by FIFRA.

17. Section 2(q)(1)(A), 7 U.S.C. § 136(q)(1)(A), defines misbranded as labeling bearing any statement which is false or misleading in any particular.

18. 40 C.F.R. § 156.10(a)(5)(ix) states, in pertinent part, that pursuant to Section 2(q)(1)(A) of FIFRA, a device that is subject to FIFRA pursuant to 40 C.F.R. § 152.500, is misbranded if its labeling is false or misleading including if it makes claims about the safety of the device.

19. 40 C.F.R. § 152.500 sets forth the requirements for devices under FIFRA.

20. The term “device” is defined at Section 2(h) of FIFRA, 7 U.S.C. § 136(h) as any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest.

21. The term “pest” is defined at Section 2(t) of FIFRA, 7 U.S.C. § 136(t) as, in pertinent part, any form of virus, bacteria, or other micro-organism. See also 40 C.F.R. § 152.5(d).

22. The term “person” is defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s), as any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

23. The term “to distribute or sell” is defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), as “to distribute, sell, offer for sale, hold for distribution, hold for shipment, or receive and (having so received) deliver or offer to deliver.

Factual Allegations and Alleged Violations

24. Respondent is, and was at all times relevant to this CAFO, a corporation and, therefore, is a “person” as that term is defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

25. Respondent is, and was at all times relevant to this CAFO, an “importer” as that term is defined in 19 C.F.R. § 101.1.

26. M.O.T. Intermodal Shipping USA Inc., located at 1200A Scottsville Road, Rochester, New York, 14624, is the resident agent for Viscor pursuant to 19 C.F.R. § 141.18.

27. **VioSafe® Surgical/Cleanroom Troffer** is a device as defined by FIFRA and its regulations.

28. Viscor imported 130 units of a device, **VioSafe® Surgical/Cleanroom Troffer**, item number VSG-24-80-40-10-UNV-N, from Canada to the United States, which arrived in the United States on or about June 24, 2019.

29. Viscor did not submit a NOA to the EPA prior to the arrival of the 130 units of **VioSafe® Surgical/Cleanroom Troffer**, item number VSG-24-80-40-10-UNV-N, into the United States.

30. Viscor also imported 61 units of a device, **VioSafe® Surgical/Cleanroom Troffer**, item number VSG-22-80-40-05-UNV-N, from Canada to the United States, which arrived in the United States on or about June 24, 2019.

31. Viscor did not submit a NOA to the EPA prior to the arrival of the 61 units of **VioSafe® Surgical/Cleanroom Troffer**, item number VSG-22-80-40-05-UNV-N, into the United States.

32. On or about June 28, 2019, Viscor electronically submitted two incomplete NOAs to the EPA for the import shipment of **VioSafe® Surgical/Cleanroom Troffer**, item numbers VSG-24-80-40-10-UNV-N and VSG-22-80-40-05-UNV-N.

33. On or about July 26, 2019, Viscor submitted, in paper format, a corrected and complete NOA to the EPA for each of the two versions or item numbers of **VioSafe® Surgical/Cleanroom Troffer** in the import shipment.

34. Each of the two versions or item numbers of **VioSafe® Surgical/Cleanroom Troffer** in the import shipment were labeled with the name of the product, "VioSafe," on the label.

35. On or about August 6, 2019, EPA requested that U.S. Customs and Border Protection Redeliver and Deny/Refuse the import shipment of **VioSafe® Surgical/Cleanroom Troffer**, item numbers VSG-24-80-40-10-UNV-N and VSG-22-80-40-05-UNV-N, because the name "VioSafe®" was false or misleading and therefore misbranded.

36. Each of the versions or item numbers of **VioSafe® Surgical/Cleanroom Troffer** in the import shipment were shipped to a person in Sioux Falls, South Dakota on or about June 27, 2019.

Counts 1-2

37. The preceding paragraphs are incorporated by reference.

38. Respondent's failure to submit two NOAs to the EPA prior to the arrival of the import shipment of **VioSafe® Surgical/Cleanroom Troffer** that arrived in the United States on

or about June 24, 2019, constitutes a violation of Section 12(a)(2)(N) of FIFRA on two separate occasions.

39. Respondent's two violations of Section 12(a)(2)(N) of FIFRA subjects Respondent to the issuance of an Administrative Complaint assessing a separate civil penalty under Section 14(a) of FIFRA for each of the two violations.

Counts 3-4

40. The preceding paragraphs are incorporated by reference.

41. All the units in the import shipment of **VioSafe® Surgical/Cleanroom Troffer**, item numbers VSG-24-80-40-10-UNV-N and VSG-22-80-40-05-UNV-N, were misbranded, because the units were labeled with the name of the product, "VioSafe," on the label, which is a false and misleading claim about the safety of the device. See also 40 C.F.R. § 156.10(a)(5)(ix).

42. Respondent's June 27, 2019 distribution or sale of the misbranded devices **VioSafe® Surgical/Cleanroom Troffer**, item numbers VSG-24-80-40-10-UNV-N and VSG-22-80-40-05-UNV-N, to a person in Sioux Falls, South Dakota, constitutes two separate violations of Section 12(a)(1)(F) of FIFRA.

43. Respondent's two violations of Section 12(a)(1)(F) of FIFRA subjects Respondent to the issuance of an Administrative Complaint assessing a separate civil penalty under Section 14(a) of FIFRA for each of the two violations.

Civil Penalty and Other Relief

44. Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4), requires the Administrator to consider the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation, when assessing an administrative penalty under FIFRA.

45. Based on an evaluation of the facts alleged in this CAFO, the factors in Section 14(a)(4) of FIFRA and EPA's Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act, dated December 2009, Complainant has determined the appropriate penalty to settle this action is \$34,323.

46. Within 30 days after the effective date of this CAFO, Respondent must pay a \$34,323 civil penalty for the FIFRA violations. Respondent must pay the penalty by electronic funds transfer, payable to the "Treasurer, United States of America," and sent to:

Federal Reserve Bank of New York
ABA No. 021030004
Account No. 68010727
SWIFT address FRNYUS33
33 Liberty Street
New York, New York 10045
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency"

In the comment or description field of the electronic funds transfer, state "Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc.," and the docket number of this CAFO.

Respondent must send a notice of payment that states Respondent's name and the case docket number to EPA at the following addresses when it pays the penalty:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Claudia Niess (ECP-17J)
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Nidhi K. O'Meara (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Blvd.

Chicago, IL 60604

47. This civil penalty is not deductible for federal tax purposes.

48. If Respondent does not pay the civil penalty in a timely manner, EPA may refer the matter to the Attorney General who will recover such amount by action in the appropriate United States district court under Section 14(a)(5) of FIFRA, 7 U.S.C. § 136l(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

49. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any amount overdue from the date payment was due at a rate established by the Secretary of the Treasury. Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a 6 percent per year penalty on any principal amount 90 days past due.

General Provisions

50. Consistent with the Standing Order Authorizing E-Mail Service of Orders and Other Documents Issued by the Regional Administrator or Regional Judicial Officer under the Consolidated Rules, dated March 27, 2015, the parties consent to service of this CAFO by e-mail at the following valid e-mail addresses for their respective attorneys: omeara.nidhi@epa.gov (for Complainant), and bwneuschafer@bclplaw.com (for Respondent). The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

51. This CAFO resolves only Respondent's liability for federal civil penalties for the violations and facts alleged in this CAFO.

52. This CAFO does not affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

53. This CAFO does not affect Respondent's responsibility to comply with FIFRA and other applicable federal, state, and local laws.

54. This CAFO is a "final order" for purposes of EPA's Enforcement Response Policy for FIFRA.

55. The terms of this CAFO bind Respondent, its successors, and assigns.

56. Each person signing this agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

57. Each party agrees to bear its own costs and attorney's fees, in this action.

58. This CAFO constitutes the entire agreement between the parties.

In the Matter of:

Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc.,

Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc., Respondent

10/16/19
Date

Katharine Wozniak
Katharine Wozniak, Vice President Customs Operations
M.O.T. Intermodal Shipping USA, Inc.
U.S. Agent for Viscor, Inc.

In the Matter of:

Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc.

United States Environmental Protection Agency, Complainant

10/29/19

Date

Sara Bruner
for Michael D. Harris, Director
Enforcement & Compliance Assurance Division

In the Matter of:

Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc.,

Docket No.

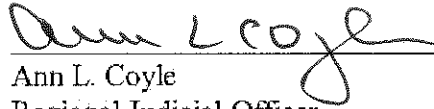
FIFRA-05-2020-0001

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

11/1/19

Date



Ann L. Coyle

Regional Judicial Officer

United States Environmental Protection Agency

Region 5

Consent Agreement and Final Order

In the matter of: Viscor Inc., in care of its US Agent M.O.T. Intermodal Shipping USA Inc.
Docket Number **FIFRA-05-2020-0001**

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Consent Agreement and Final Order**, docket number FIFRA-05-2020-0001, which was filed on November 4, 2019, in the following manner to the following addressees:

Copy by E-mail to
Attorney for Complainant:

Ms. Nidhi K. O'Meara
omeara.nidhi@epa.gov

Copy by E-mail to
Attorney for Respondent:

Mr. Brandon Neuschafer
bwneuschafer@bclplaw.com

Copy by E-mail to
Regional Judicial Officer:

Ann Coyle
coyle.ann@epa.gov

Dated

November 4, 2019



Dawn Whitehead
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 5