

U. S. ENVIRONMENTAL PROTECTION AGENCY
REGION 7
11201 RENNER BOULEVARD
LENEXA, KANSAS 66219

UNITED STATES
ENVIRONMENTAL PROTECTION
AGENCY-REGION 7

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BEFORE THE ADMINISTRATOR

In the Matter of)
) Docket No. FIFRA-07-2014-0014
Integrated Environmental Technologies)
)
Respondent)

CONSENT AGREEMENT AND FINAL ORDER

The U.S. Environmental Protection Agency (EPA), Region 7 and Integrated Environmental Technologies, Inc. (Respondent) have agreed to a settlement of this action before filing of a Complaint, and thus this action is simultaneously commenced and concluded pursuant to Rules 22.13(b) and 22.18(b)(2) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Renovation, Termination or Suspension of Permits (Consolidated Rules), 40 C.F.R. §§ 22.13(b) and 22.18(b)(2).

Section I

Jurisdiction

1. This proceeding is an administrative action for the assessment of civil penalties instituted pursuant to Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l.

2. This Consent Agreement and Final Order (CAFO) serves as notice that the EPA has reason to believe that Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

Section II

Parties

3. The Complainant, by delegation from the Administrator of the EPA and the Regional Administrator, EPA, Region 7, is the Director of the Water, Wetlands and Pesticides Division, EPA, Region 7.

4. The Respondent is Integrated Environmental Technologies, Inc., a pesticide registrant and distributor located at 4235 Commerce Street, in Little River, South Carolina.

Section III

Statutory and Regulatory Background

5. Congress enacted FIFRA in 1947 and amended it in 1972 and in 1996. The general purpose of FIFRA is to provide the basis for regulation, sale, distribution, and use of pesticides in the United States. 7 U.S.C. 136 et seq.

6. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines the term “person” to mean any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

7. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term “to distribute or sell” to mean “to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver.”

8. Section 2(p) of FIFRA, 7 U.S.C. § 136(p), defines the term “label” to include “the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers,” and the term “labeling” as meaning “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 or device.”

9. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term “pesticide” to include “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest,” and “any substance or mixture of substances intended for use as a plant regulator [...]”

10. Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), states that it shall be unlawful for any person to distribute or sell any pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as part of the statement required in connection with its registration.

11. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states it shall be unlawful for any person to distribute or sell any pesticide which is misbranded.

12. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(A), states that a pesticide is misbranded if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular.

13. The regulation at 40 C.F.R. § 156.10(a)(5) provides that the labeling for a pesticide or device is false or misleading if it contains, *inter alia*:

- (i) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- (ii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- (iii) Claims as to the safety of the pesticide or its ingredients; or
- (iv) Non-numerical and/or comparative statements on the safety of the product, including but not limited to: “Contains all natural ingredients,”

“Among the least toxic chemicals known,” and “Pollution approved.”

14. Section 2(q)(1)(E) of FIFRA, 7 U.S.C. § 136(q)(E), states that a pesticide is misbranded if any word, statement, or other information required by or under authority of FIFRA to appear on the label or labeling is not prominently placed thereon.

15. Section 2(q)(1)(F) of FIFRA, 7 U.S.C. § 136(q)(F), states that a pesticide is misbranded if the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under Section 3(d) of FIFRA, are adequate to protect health and the environment.

16. Pesticide registrants may distribute or sell a registered product under another person's name and address instead of (or in addition to) their own. Such distribution and sale is termed "supplemental distribution." 40 C.F.R. § 152.132. The distributor is considered an agent of the registrant for all intents and purposes under FIFRA, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product. Supplemental distribution is permitted upon notification to EPA if specific conditions, stated at 40 C.F.R. § 152.132(a) through (e), are met. As a requirement of supplemental distribution, the label of the distributor product must be the same as that of the registered product, with exceptions stated at 40 C.F.R. § 152.132(d)(1) through (5).

Section IV

General Factual Allegations

17. Respondent is, and at all times referred to herein was, a “person” within the meaning of FIFRA.

18. Respondent Integrated Environmental Technologies, Inc., is the registrant for EcaFlo Anolyte (aka Excelyte), EPA Reg. No. 82341-1.
19. Respondent has a supplemental distribution agreement with Seriously Clean, Ltd., of Nixa, Missouri (the “supplemental distributor”), to distribute EcaFlo Anolyte, EPA Reg. No. 82341-1, under the distributor product name, Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098.
20. On or about August 19, 2010, the EPA Office of Pesticides Programs, Registration Division, accepted a label (“accepted label”) for the product EcaFlo Anolyte, EPA Reg. No. 82341-1, that was submitted by the Respondent.
21. The “accepted label” and any subsequent amendments are a part of the statement required by the registrant in connection with its registration of the product under Section 3 of FIFRA, 7 U.S.C. § 136a.
22. The “accepted label” and any subsequent amendments identify the label language accepted by EPA for a particular registered pesticide product, including those distributed under a supplemental distribution agreement.
23. Any changes in labeling that differs in substance from the labeling for EcaFlo Anolyte, EPA Reg. No. 82341-1, accepted by the Office of Pesticides Program, Registration Division, must be submitted by the registrant to and accepted by Office of Pesticides Program, Registration Division prior to use in commerce.
24. On or about September 4, 2012, a representative of the Missouri Department of Agriculture (MDA) conducted an investigation of Seriously Clean, Ltd., Respondent’s supplemental distributor, and documented that the supplemental distributor had distributed Nixall Disinfectant + Cleanser, under EPA Reg. No. 82341-1-88098. Subsequently, the MDA

forwarded information from its investigation to the EPA, including copies of product labels, order summaries, and invoices.

25. Following the MDA inspection, the EPA documented that Seriously Clean, Ltd.'s website at <http://www.nixall.com> offered for sale the product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098.

26. The Directions for Use for the EPA-accepted label for EcaFlo Anolyte states that "Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes."

27. The Directions for Use on the label for the 2-ounce bottle of Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, lacked the statement, "Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes."

28. The Directions for Use for the EPA-accepted label for EcaFlo Anolyte in effect at the time of the MDA inspection include contact times for the following five pathogens:

Salmonella enterica ATCC 10708, Pseudomonas aeruginosa ATCC 15442, Staphylococcus aureus ATCC 6538, Staphylococcus aureus MRSA ATCC 33591, and Swine Influenza virus H1N1 ATCC VR-99.

29. The pesticide product Nixall Disinfectant + Cleanser is marketed as being made with "Anolyte Water," in conjunction with claims that Anolyte Water "kills 99.99% of viruses," and that it is "up to 100 times more efficient against bacteria than bleach."

30. The pesticide products Nixall Disinfectant + Cleanser is marketed as being made with "Anolyte Water," in conjunction with claims of Anolyte Water's effectiveness against:

- Adenovirus
- Aspergillus niger
- Avium-intracellulare
- Bacillus anthracis
- Botrytis cinerea
- Botulinum toxin
- Brucellosis
- Campylobacter
- Candida albicans

- Candida albicans
- Coliphages
- Corynebacterium amycolatum
- Dermatomycolosis
- E. coli
- Entamoeba histolytica
- Enterobacter aerogenes
- Enterobacter cloacae
- Enterococcus
- Enterococcus faecalis
- Fungi
- General coliform bacteria
- Glanders
- H. pylori
- Haemophilus influenza
- Hepatitis B
- Hepatitis C
- HIV
- HIV-1
- Klebsiella Pneumonia
- Listeria monocytogenes
- M. avium
- M. chelonae
- M. chelonae
- M. luteus
- M. smegmatis
- M. xenopi
- Mold
- Monilia jructicola
- MRSA
- Mycobacterium
- Mycobacterium tuberculosis
- Noroviruses
- Plague
- Poliovirus
- Proteus
- Proteus mirabilis
- Pseudomonas aeruginosa
- Pseudomonas fluorescens
- S. dublin
- S. haemolyticus
- S. hominis
- S. pullorum
- S. saprophyticus
- Salmonella enteric
- Serratia marcescens
- Staphylococcus aureus
- Streptococcus faecalis
- Streptococcus pyogenes
- Sulfate Reducing bacteria
- Thermo-tolerant coliform
- Tularemia
- Vancomycin Resistant spores of H. pylori
- Yeast

Of the above pathogens, only Pseudomonas aeruginosa, Staphylococcus aureus, and Salmonella enteric are listed on the EPA-accepted label for EcaFlo Anolyte, EPA Reg. No. 82341-1, in effect at the time of the inspection referenced above.

Violations

31. The Complainant hereby states and alleges that Respondent has violated FIFRA and federal regulations promulgated thereunder, as follows:

Counts 1-399

Sales/Distribution of Nixall Disinfectant + Cleanser

32. The facts stated in Paragraphs 17 through 30 are realleged and incorporated as if fully stated herein.

33. On at least 8 separate dates, Seriously Clean, Ltd., Respondent's supplemental distributor, offered for sale on the Internet the registered pesticide product EcaFlo Anolyte, EPA Reg. No. 82341-1, under the product name Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, including on or about January 9, 2012; January 10, 2012; February 10, 2012; April 23, 2012; August 4, 2012; August 5, 2012; August 6, 2012; and August 15, 2012.

34. On 391 occasions during the year 2012, Seriously Clean, Ltd., sold or distributed a quantity of the registered pesticide product EcaFlo Anolyte, EPA Reg. No. 82341-1, under the product name Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098.

35. The registered pesticide product EcaFlo Anolyte, EPA Reg. No. 82341-1, in its directions for use on the accepted label, states:

- (i) it is designed for "disinfecting hard, non-porous environmental surfaces."
- (ii) It is for use "in public – or – common places where bacteria may be of concern on hard, non-porous surfaces."
- (iii) It is to be applied at its formulated strength of 500 ppm free available chlorine to hard non-porous surfaces, which must remain wet for 10 minutes for disinfection.
- (iv) It is not recommended for use on fabrics.
- (v) It is to be used for water treatment only in oil and gas applications such as dosing frac water, water flood injection water, and oil and gas transmission lines.

36. Seriously Clean, Ltd.'s website, www.nixall.com, is referenced on the label for the product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, and the website contents are "labeling" as defined by Section 2(p) of FIFRA, 7 U.S.C. § 136(p).

37. Seriously Clean, Ltd.'s labeling for the product EcaFlo Anolyte, EPA Reg. No. 82341-1, supplementally distributed as Nixall Disinfectant + Cleanser, included the following directions for use:

- (i) "For general purpose sanitizing and protecting, dilute 10:1 with water."
- (ii) "Kitchen wash cloths and sponges are loaded with bacteria. Treat with Nixall;"
- (iii) "[for] Water treatment;" and
- (iv) "Nixall can be diluted with water in a ratio of 15:1 without losing any effectiveness."

38. In addition, in 108 of the 391 documented transactions during the year 2012, Seriously Clean, Ltd. sold or distributed a quantity in four-packs of two-ounce bottles of the registered pesticide product EcaFlo Anolyte, EPA Reg. No. 82341-1, under the product name Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098.

39. The label for the pesticide product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, distributed by Seriously Clean, Ltd. in four-packs of two-ounce bottles, lacked required precautionary statements from the EPA-accepted label directing users to rinse food contact surfaces with potable water and not to use the product on utensils, glasses, or dishes.

40. The labeling for the pesticide product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, distributed by Seriously Clean, Ltd. in four-packs of two-ounce bottles, was not securely attached as required by 40 C.F.R. 156.10(i)(1)(ii)..

41. Seriously Clean, Ltd. made the following claims as part of the distribution or sale of Nixall Disinfectant + Cleanser:

- (i) "Accelerates healing of wounds;"

- (ii) “For mold and mildew destruction;”
- (iii) “[for use on] bathtubs and sinks to control mold and mildew;”
- (iv) “[for use on] shower stalls to eliminate athletes foot fungus.”
- (v) “Eliminates 99.99% of viruses;”
- (vi) “Eliminates Salmonella and E. coli;”
- (vii) “Destroys viruses, bacteria, fungi, mold;”
- (viii) “Removes biofilm;”
- (ix) Use “to eliminate all possible viruses, bacteria, fungus and mold;”
- (x) “Kills anthrax spores on contact;” and
- (xi) “Neutralizes sarin gas, mustard gas, and nerve gas.”

42. Seriously Clean, Ltd. made the following claims as part of the distribution or sale of Nixall Disinfectant + Cleanser:

- (i) “Water house plants to oxygenate and stimulate growth;”
- (ii) “Stimulate growth of plants, improve flowering and yield;”
- (iii) “Oxygenate the air around your pet, watch the results;”
- (iv) “Destroys Algae and Legionella;” and
- (v) “will eliminate viruses and bacteria and do it without the risk of mutation;”

43. Seriously Clean, Ltd. made the following claims in the product labeling or as part of the distribution or sale of Nixall Disinfectant + Cleanser:

- (i) “Any problem Nixall™ is safe to use at full strength;”
- (ii) “as safe as water;” and
- (iii) “safer and more affordable than toxic cleaners.”

44. The pesticide product Nixall Disinfectant + Cleanser is misbranded, in that its labeling contains statements regarding its use that conflict with the directions for use on the accepted label for the product EcaFlo Anolyte, EPA Reg. No. 82341-1, and are thus false or misleading.

45. The pesticide product Nixall Disinfectant + Cleanser is misbranded, in that its labeling contains false or misleading statements regarding the safety of the product.

46. The pesticide product Nixall Disinfectant + Cleanser is misbranded, in that its labeling contains false or misleading statements about the value of the product for purposes other than as a pesticide or device.

47. The pesticide product Nixall Disinfectant + Cleanser is misbranded, in that the product as distributed in four-packs of two-ounce bottles, lacked information required to appear on the label.

48. Claims on the labelling for the product Nixall Disinfectant + Cleanser differ substantially from claims made for the product EcaFlo Anolyte, EPA Reg. No. 82341-1 as part of the statement required in connection with that product's registration.

49. The pesticide product EcaFlo Anolyte, EPA Reg. No. 82341-1, supplementally distributed as Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, was distributed or sold by Seriously Clean, Ltd. in conjunction with marketing claims that differed substantially from the claims on the statement required in connection with its registration.

50. On the occasion of each of the sales or distributions, or offering for sale or distribution, of the product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, as alleged above, Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), in that it sold or distributed a pesticide which was misbranded.

51. On the occasion of each of the sales or distributions, or offering for sale or distribution, of the product Nixall Disinfectant + Cleanser, EPA Reg. No. 82341-1-88098, as alleged above, Respondent violated Section 12(a)(1)(B) of FIFRA, 7 U.S.C. § 136j(a)(1)(B), in that it sold or distributed a pesticide in conjunction with claims that differed substantially than those on the statement required in connection with its registration..

Section V

Consent Agreement

52. For purposes of this proceeding, Respondent admits the jurisdictional allegations set forth above.

53. Respondent neither admits nor denies the factual allegations set forth above.

54. Respondent waives its right to contest any allegations set forth above and its right to appeal the Final Order accompanying this Consent Agreement.

55. Respondent and the EPA agree to conciliate this matter without the necessity of a formal hearing and to bear their respective costs and attorney's fees.

56. Nothing contained in the Final Order portion of this CAFO shall alter or otherwise affect Respondent's obligation to comply with all applicable federal, state, and local environmental statutes and regulations and applicable permits.

57. The undersigned representative of Respondent certifies that he or she is fully authorized to enter into the terms and conditions of this CAFO and to execute and legally bind Respondent to it.

58. By signing this CAFO, Respondent certifies, to the best of its knowledge, that it is presently in compliance with FIFRA, 7 U.S.C. § 136 et seq., and all regulations promulgated thereunder, and that it is no longer selling, distributing, or offering for sale or distribution any unregistered products that are required to be registered with the EPA by the statute.

59. The effect of settlement described in the following paragraph is conditioned upon the accuracy of the Respondent's representations to the EPA, as memorialized in the preceding paragraph.

60. Respondent consents to the issuance of the Final Order hereinafter recited and consents to the payment of a civil penalty as specified in the Final Order. Payment of this civil penalty in full shall resolve all civil and administrative claims for all violations of FIFRA alleged in this document.

61. Complainant reserves the right to take any enforcement action with respect to any other violations of FIFRA or any other applicable law.

Late Payment Provision

62. Under 31 U.S.C. § 3717, the EPA is entitled to assess interest and penalties on debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Respondent understands that its failure to timely pay any portion of the civil penalty described in Paragraph 1 of the Final Order may result in the commencement of a civil action in Federal District Court to recover the full remaining balance, along with penalties and accumulated interest. In such case, interest shall accrue thereon at the applicable statutory rate on the unpaid balance until such civil or stipulated penalty and any accrued interest are paid in full. A late payment handling charge of \$15 will be imposed after thirty (30) days and an additional \$15 will be charged for each subsequent thirty (30) day period. Additionally, as

provided by 31 U.S.C. § 3717(e)(2), a six percent (6%) per annum penalty (late charge) may be assessed on any amount not paid within ninety (90) days of the due date.

Section VI

Final Order

Pursuant to Section 14 of FIFRA, as amended, 7 U.S.C. §136l, and according to the terms of the Consent Agreement set forth above, **IT IS HEREBY ORDERED THAT:**

1. Within thirty (30) days of the effective date of this CAFO, Respondent shall pay a civil penalty of Eighty-Seven Thousand, Three Hundred and Forty-Four Dollars (\$87,344.00).

The payment shall identify Respondent by name and docket number and shall be by online payment, certified or cashier's check, or wire transfer, as directed below.

2. Payment of the penalty may be submitted on-line at www.pay.gov by entering "SFO 1.1" in the "Search Public Forms" field. Open the on-line form and complete required fields to complete payment. Respondent shall print a copy of the payment receipt and mail a copy of the receipt to the contacts listed below.

3. Payments by certified or cashier's check shall be made payable to the "United States Treasury" and sent to:

U.S. Environmental Protection Agency, Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, Missouri 63197-9000.

4. Wire transfers should be directed to the Federal Reserve Bank of New York:

Federal Reserve Bank of New York
ABA = 021030004
Account = 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”

5. A copy of the check or other information confirming payment shall simultaneously be sent to the following:

Regional Hearing Clerk
U.S. Environmental Protection Agency
Region 7
11201 Renner Boulevard
Lenexa, Kansas 66219;

and

Elizabeth Murtagh-Yaw
WWPD/TOPE
U.S. Environmental Protection Agency
Region 7
11201 Renner Boulevard
Lenexa, Kansas 66219.

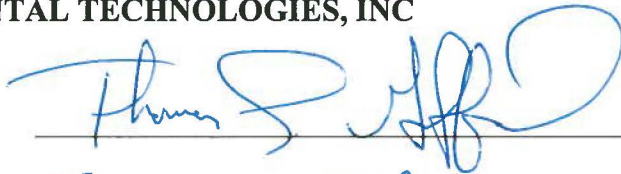
6. Respondent and Complainant shall each bear its own costs and attorneys' fees incurred as a result of this matter.

7. No portion of the civil penalty or interest paid by Respondent pursuant to the requirements of this CAFO shall be claimed by Respondent as a deduction for federal, state, or local income tax purposes.

8. This CAFO shall be effective upon the filing of the Final Order by the Regional Hearing Clerk for the EPA, Region 7. Unless otherwise stated, all time periods stated in this CAFO shall be calculated in calendar days from such date.

RESPONDENT
INTEGRATED ENVIRONMENTAL TECHNOLOGIES, INC

Date: 3/14/15

By: 

Thomas S. Gifford
Print Name

EVP + CFO
Title

COMPLAINANT

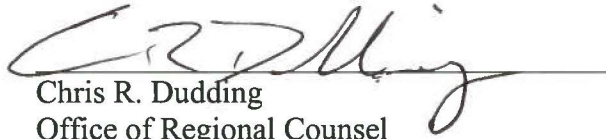
U. S. ENVIRONMENTAL PROTECTION AGENCY

Date: 3-18-15



Karen Flournoy
Director
Water, Wetlands and Pesticides Division

Date: 3/18/15



Chris R. Dudding
Office of Regional Counsel

IT IS SO ORDERED. This Order shall become effective immediately.

Date: 3-30-2015

Karina Borromeo

KARINA BORROMEO
Regional Judicial Officer

IN THE MATTER OF Integrated environmental Technologies, Respondent
Docket No. FIFRA-07-2014-0014

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Order was sent this day in the following manner to the addressees:

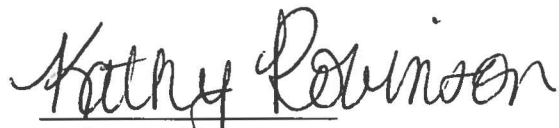
Copy by email to Attorney for Complainant:

dudding.chris@epa.gov

Copy by First Class Mail to:

Daniel B. Schulson
Associate
Beveridge & Diamond, P.C.
1350 I Street, N.W. Suite 700
Washington, DC 20005

Dated: 3/30/15



Kathy Robinson
Hearing Clerk, Region 7