



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

JAN 15 2009

REPLY TO THE ATTENTION OF:
LC-8J

CERTIFIED MAIL

Receipt No. 7001 0320 0006 0183 0241

Eric Schriver, President
Colténe/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223

In the Matter of: Colténe/Whaledent, Inc. Docket No. FIFRA-05-2009-0002
(Corrected Transmittal Letter)

Dear Mr. Schriver:

I have enclosed the Complaint filed by the U.S. Environmental Protection Agency, Region 5, against Colténe/Whaledent, Inc., under Section 14(a) of the FIFRA, 7 U.S.C § 136l (a).

As provided in the Complaint, if you wish to request a hearing, you must do so in your answer to the Complaint. Please note that if you do not file an answer with the Regional Hearing Clerk (E-13J), U.S. EPA, Region 5, 77 West Jackson Blvd., Chicago, IL 60604 within 30 days of your receipt of this Complaint, a default order may be issued and the proposed civil penalty will become due 30 days later.

In addition, whether or not you request a hearing, you may request an informal settlement conference. If you wish to request a conference, or if you have any questions about this matter, please contact Robert Guenther, Associate Regional Counsel at (312) 886-0566.

Sincerely,

A handwritten signature in cursive script that reads "Joseph G. Lukascyk".

Joseph G. Lukascyk
Pesticides and Toxic Compliance Section

Enclosures

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

In the Matter of:)	Docket No. FIFRA-05-2009-0002
)	
Coltène/Whaledent, Inc.,)	Proceeding to Assess a Civil
Cuyahoga Falls, Ohio,)	Penalty under Section 14(a)
)	of the Federal Insecticide,
and)	Fungicide and Rodenticide
)	Act, 7 U.S.C. § 136l(a)
Ultronics, Inc.,)	
Cuyahoga Falls, Ohio,)	
)	
Respondents.)	
)	
)	
)	

RECEIVED
JAN - 6 2009
REGIONAL HEARING CLERK
U.S. ENVIRONMENTAL
PROTECTION AGENCY

Complaint

1. This is an administrative proceeding to assess a civil penalty under Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136l(a).
2. Complainant is, by lawful delegation, the Director of the Land and Chemicals Division, United States Environmental Protection Agency (EPA), Region 5.
3. The first Respondent is Coltène/Whaledent, Inc. (Coltène/Whaledent), a Delaware corporation doing business in the State of Ohio.
4. The second Respondent is Ultronics, Inc. (Ultronics), a Delaware corporation doing business in the State of Ohio.

Statutory and Regulatory Background

5. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it is unlawful for any person in any state to distribute or sell to any person any pesticide that is misbranded.
6. Section 12(a)(2)(B)(i) of FIFRA, 7 U.S.C. § 136j(a)(2)(B)(i), states that it is unlawful for any person to refuse to prepare, maintain or submit any information required by

Sections 7 and 8 of FIFRA, 7 U.S.C. §§ 136e and 136f.

7. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines the term “distribute or sell” as “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(u) of FIFRA, 7 U.S.C. § 136(u), defines “pesticide” as, among other things, any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

9. Section 2(t) of FIFRA, 7 U.S.C. § 136(gg), defines “pest” as any insect or any other form of terrestrial or aquatic plant or animal life which the Administrator of EPA declares to be a pest under Section 25(c)(1) of FIFRA, 7 U.S.C. § 136w(c)(1), 40 C.F.R. § 152.5(b).

10. Federal regulations, at 40 C.F.R. § 152.15(a)(1), state that a substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration, if the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) that the substance can or should be used as a pesticide.

11. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136w(q)(1)(A), states that a pesticide is misbranded if it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator under Section 25(c)(3) of FIFRA, 7 U.S.C. § 136w(c)(3).

12. Federal regulations, at 40 C.F.R. § 156.10(1), require that every pesticide product bear a label displaying, among other things, the name and address of the pesticide producer or registrant and the pesticide producing establishment number in a clear and prominent manner.

13. Federal regulations, at 40 C.F.R. § 169.2(a), promulgated pursuant to Section 8(a) of FIFRA, 7 U.S.C. § 136f(a), require that all producers of pesticides must prepare and maintain records showing the product name, EPA registration number, amounts per batch and batch identification of all pesticides produced.

14. Federal regulations, at 40 C.F.R. § 169.2(c), which was promulgated pursuant to Section 8(a) of FIFRA, 7 U.S.C. § 136f(a), require that all producers of pesticides must prepare and maintain records reflecting the manufacture of all pesticides, including the brand name of the pesticides, name and address of any shippers and carriers, dates delivered and quantities received.

15. The Administrator of EPA may assess a civil penalty against any dealer, retailer or other distributor who violates any provision of FIFRA of up to \$5,500 for each offense occurring from January 31, 1997, through March 15, 2004, pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

General Allegations

16. Respondents are “persons” as defined at Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

17. Respondent Coltène/Whaledent is the North American subsidiary of an international manufacturer and distributor of professional dental care and hygiene products based in Altstätten, Switzerland, know as Coltène/Whaledent, AG.

18. Respondent Ultronics is a subsidiary owned or controlled by Respondent Coltène/Whaledent.

19. During calendar year 2004, Respondents owned or operated a place of business located at 235 Ascot Parkway, Cuyahoga Falls, Ohio 44223, which was assigned the pesticide producing establishment number of 61584-OH-1. This facility manufactures or produces

products marketed as pesticides.

20. On January 6, 2004, Respondent Coltène/Whaledent held for sale at its facility in Cuyahoga Falls “BioSonic Germicidal Ultrasonic Cleaner Concentrate,” which is assigned pesticide product registration number 211-36-61584 and was manufactured at the Cuyahoga Falls facility. This substance is a “pesticide,” as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

21. On January 6, 2004, Respondent Ultrionics held for sale at its facility in Cuyahoga Falls “Ultrasonic 10 Minute Instrument Disinfectant,” which is assigned pesticide product registration number 211-36-63562 and was manufactured at the Cuyahoga Falls facility. This substance is a “pesticide,” as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

22. On January 6, 2004, Respondent Ultrionics held for sale at its facility in Cuyahoga Falls “Ultracare Disinfectant Cleaner/Deodorizer Concentrate,” which is assigned pesticide product registration number 61178-1-63562 and was manufactured at the Cuyahoga Falls facility. This substance is a “pesticide,” as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

COUNT I

23. Complainant realleges paragraphs 1 - 22 as if restated here in full.

24. On January 6, 2004, “BioSonic Germicidal Ultrasonic Cleaner Concentrate,” assigned pesticide product registration number of 211-36-61584 and offered for sale by Respondent Coltène/Whaledent, bore a pesticide producer establishment number of 211-KS-1.

25. Respondent Coltène/Whaledent offered for sale a product which was not labeled with the correct pesticide producer establishment number, in violation of 40 C.F.R. § 156.10(a)(1)(v).

26. Respondent Coltène/Whaledent's offering for sale of a pesticide bearing an incorrect pesticide producer establishment number constitutes the sale of a misbranded pesticide, which is an unlawful act under Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

27. Respondent Coltène/Whaledent's unlawful act under Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), renders it liable for a penalty not to exceed \$5,500 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

COUNT II

28. Complainant realleges paragraphs 1 - 22 as if restated here in full.

29. On January 6, 2004, "Ultrasonic 10 Minute Instrument Disinfectant," assigned a pesticide product registration number of 211-36-63562 and offered for sale by Respondent Ultrionics, bore a pesticide producer establishment number of 211-KS-1 and a pesticide producer's address of 750 Corporate Drive, Mahwah, New Jersey 07430.

30. Respondent Ultrionics offered for sale a product which was not labeled with the correct address of the pesticide producer, in violation of 40 C.F.R. § 156.10(a)(1)(ii).

31. Respondent Ultrionics offered for sale a product which was not labeled with the correct pesticide producer establishment number, in violation of 40 C.F.R. § 156.10(a)(1)(v).

32. Respondent Ultrionics offered for sale a product which was not labeled with the correct pesticide producer establishment number, in violation of 40 C.F.R. § 156.10(a)(1)(v).

33. Respondent Ultrionics' violation of Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), renders it liable for a penalty not to exceed \$5,500 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

COUNT III

34. Complainant realleges paragraphs 1 - 22 as if restated here in full.

35. On January 6, 2004, "Ultracare Disinfectant Cleaner/Deodorizer Concentrate," assigned pesticide product registration number of 61178-1-63562 and offered for sale by Respondent Ultrionics, bore a pesticide producer establishment number of 37365-PA-01.

36. Respondent Ultrionics offered for sale a product which was not labeled with the correct pesticide producer establishment number, in violation of 40 C.F.R. § 156.10(a)(1)(v).

37. Respondent Ultrionics' offering for sale of a pesticide bearing an incorrect pesticide producer establishment number constitutes the sale of a misbranded pesticide, which is an unlawful act under Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

38. Respondent Ultrionics' unlawful act under Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), renders it liable for a penalty not to exceed \$5,500 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

COUNT IV

39. Complainant realleges paragraphs 1 - 22 as if restated here in full.

40. On January 6, 2004, Respondent Coltène/Whaledent had not prepared and maintained records containing the pesticide product registration numbers of all pesticides produced, in violation of 40 C.F.R. § 169.2(a).

41. On January 6, 2004, Respondent Coltène/Whaledent had not maintained records reflecting the receipt of pesticides and active ingredients produced by other entities, including the brand name of the received pesticides, the name and address of the shippers, the name of the delivering carrier and dates and quantities received, in violation of 40 C.F.R. § 169.2(c).

42. Respondent Coltène/Whaledent's failure to prepare and maintain records as required by 40 C.F.R. § 169.2(a) and (c) is an unlawful act pursuant to Section 12(a)(2)(B)(i) of FIFRA, 7 U.S.C. § 136j(a)(2)(B)(i).

43. Respondent Coltène/Whaledent's unlawful act under Section 12(a)(2)(B)(i) of FIFRA, 7 U.S.C. § 136j(a)(2)(B)(i), renders it liable for a penalty not to exceed \$5,500 pursuant to Section 14(a)(1) of FIFRA, 7 U.S.C. § 136l(a)(1), and 40 C.F.R. Part 19.

Proposed Civil Penalty

44. Complainant proposes that the Administrator assess a civil penalty against Respondents for the violations alleged in this Complaint as follows:

Count 1 (Coltène/Whaledent)

Distribution/sale of a misbranded pesticide "BioSonic Germicidal Ultrasonic Cleaner Concentrate," EPA Reg. No. 211-36-61584:
7 U.S.C. § 136j(a)(1)(E).....\$4,400

Count 2 (Ultronics)

Distribution/sale of a misbranded pesticide "Ultronics 10 min. Instrument Disinfectant," EPA Reg. No. 211-36-63562:
7 U.S.C. § 136j(a)(1)(E).....\$4,400

Count 3 (Ultronics)

Distribution/sale of a misbranded pesticide "Ultracare Disinfectant Cleaner/Deodorizer Concentrate," EPA Reg. No. 61178-1-63562:
7 U.S.C. § 136j(a)(1)(E).....\$4,400

Count 4 (Coltène/Whaledent)

Failure to maintain proper production and receipt records:
7 U.S.C. § 136j(a)(2)(B)(i).....\$5,500

Total Proposed Civil Penalty \$18,700

45. Complainant determined the proposed civil penalty according to Section 14(a) of FIFRA, 7 U.S.C. § 136l(a). In determining the penalty amount, Complainant considered the size of Respondents' business, the effect on Respondents' ability to continue in business and the gravity of the violation. Complainant also considered EPA's *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act*, dated July 2, 1990, a copy of which

accompanies this Complaint.

Rules Governing this Proceeding

46. The *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits* (the Consolidated Rules), at 40 C.F.R. Part 22, govern this proceeding to assess a civil penalty. A copy of the Consolidated Rules accompanies this Complaint.

Filing and Service of Documents

47. Respondents must file with the EPA Regional Hearing Clerk the original and one copy of each document Respondents intend to be part of the record in this proceeding. The Regional Hearing Clerk's address is:

Regional Hearing Clerk (E-13J)
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604

48. Respondents must serve a copy of each document filed in this proceeding on each party pursuant to Section 22.5 of the Consolidated Rules. Complainant has authorized Robert S. Guenther, Associate Regional Counsel, to receive any answer and subsequent legal documents that Respondents serve in this proceeding. You may telephone Mr. Guenther at: (312) 886-0566. His address is:

Robert S. Guenther (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604

Terms of Payment

49. Respondents may resolve this proceeding at any time by paying the proposed penalty by sending a certified or cashier's check, payable to "Treasurer, United States of

America," to:

U.S. EPA
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

50. Respondents must include the case name, any assigned docket number or billing document number on the check and in the letter transmitting the check. Respondent must simultaneously send copies of the check and transmittal letter to the Regional Hearing Clerk and Mr. Guenther at the addresses given above, and to:

Joseph G. Lukascyk (LC-8J)
Pesticides and Toxics Compliance Section
U.S. EPA, Region 5
77 W. Jackson Blvd.
Chicago, IL 60604

Answer and Opportunity to Request a Hearing

51. If a Respondent contests any material fact upon which this Complaint is based, contends that the proposed penalty is inappropriate or contends that it is entitled to judgment as a matter of law, that Respondent may request a hearing before an Administrative Law Judge. To request a hearing, that Respondent must file a written Answer within 30 days of receiving this Complaint and must include in that written Answer a request for a hearing. Any hearing will be conducted according to the Consolidated Rules.

52. In counting the 30-day period mentioned above, the date of receipt is not counted, but Saturdays, Sundays, and federal legal holidays are counted. If the 30-day period expires on a Saturday, Sunday, or federal legal holiday, the time period extends to the next business day.

53. To file an Answer, Respondents must file the original written Answer and one copy with the Regional Hearing Clerk at the address specified above and must serve copies of the

Answer on the other parties.

54. A Respondent's written Answer must clearly and directly admit, deny, or explain each of the factual allegations in the Complaint or must state clearly that that Respondent has no knowledge of a particular factual allegation. Where a Respondent states that it has no knowledge of a particular factual allegation, the allegation is deemed denied. A Respondent's failure to admit, deny, or explain any material factual allegation in the Complaint constitutes an admission of the allegation.

55. A Respondent's answer must also state:

- a. Any circumstances or arguments which that Respondent alleges constitute grounds of defense;
- b. Any facts that Respondent disputes;
- c. Any basis for opposing the proposed penalty; and
- d. Whether that Respondent requests a hearing.

Settlement Conference

56. Whether or not Respondents request a hearing, Respondents may request an informal conference to discuss the facts alleged in the Complaint and to discuss settlement. To request an informal settlement conference, a Respondent may contact Mr. Guenther at the address or phone number given in paragraph 48, above.

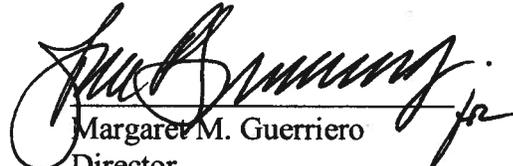
57. A Respondent's request for an informal settlement conference will not extend the 30-day period for filing a written Answer to this Complaint. A Respondent may simultaneously pursue both an informal settlement conference and the adjudicatory hearing process.

Complainant encourages all parties against whom it proposes to assess a civil penalty to pursue settlement through an informal conference. Complainant, however, will not reduce the proposed penalty because the parties hold an informal settlement conference.

Continuing Obligation to Comply

58. Payment of a civil penalty will not affect a Respondent's continuing obligation to comply with FIFRA and any other applicable federal, state or local laws.

1/6/09
Date


Margaret M. Guerriero
Director
Land and Chemicals Division

CERTIFICATE OF SERVICE

I hereby certify that the original signed copy of the Consent Agreement and Final Order in resolution of the civil administrative action involving Coltene/Whaledent, Inc., was filed on January 6, 2009, with the Regional Hearing Clerk (E-13J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604, and will be mailed no later than the next business day by Certified Mail, Receipt No.7001 0320 0006 0183 0272, a copy of the original to the Respondents:

Eric Schriver
President
Colténe/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223

and forwarded copies (intra-Agency) to:

Marcy Toney, Regional Judicial Officer, ORC/C-14J
Robert S. Guenther, Regional Judicial Officer, ORC/C-14J
Eric Volck, Cincinnati Finance/MWD



Frederick Brown
Pesticides and Toxics Compliance Section
U.S. EPA - Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604

Docket No. FIFRA-05-2009-0002

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