



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590
JUN 12 2018

REPLY TO THE ATTENTION OF:

LC-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Nancy Spencer
Director of Operations
Coltene/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223

Re: Expedited Settlement Agreement and Final Order In the Matter of
Coltene/Whaledent, Inc. Docket Number **FIFRA-05-2018-0036**

Ms. Spencer:

Enclosed please find a copy of a fully executed Expedited Settlement Agreement and Final Order in resolution of the above case. This document was filed on June 12, 2018 with the Regional Hearing Clerk.

The civil penalty in the amount of \$2,400.00 is to be paid in the manner described in paragraphs 12-13. 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 "Abigail Wesley".

Abigail Wesley
Pesticides and Toxics Compliance Section

cc: Josh Zaharoff, (C-14J)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5



In the Matter of:

Coltene/Whaledent, Inc.
Cuyahoga Falls, Ohio

Respondent.

Docket No. FIFRA-05-2018-0036

EXPEDITED SETTLEMENT
AGREEMENT AND
FINAL ORDER

EXPEDITED SETTLEMENT AGREEMENT and FINAL ORDER

1. The U.S. Environmental Protection Agency (“EPA”) alleges that Coltene/Whaledent, Inc. (“Respondent”) failed to comply with Section 7(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136e(c), for its facility, EPA Establishment Number 061584-OH-001, located at 235 Ascot Parkway, Cuyahoga Falls, Ohio 61584.

2. Section 7(c) of FIFRA, 7 U.S.C. § 136e(c) requires any producer operating a registered pesticide-producing establishment to inform EPA of the types and amounts of pesticides (and, if applicable, active ingredients used in producing pesticides): which it is producing; which it has produced during the past year; and which it has sold or distributed during the past year. In addition, § 136e(c) provides that the required information shall be kept current and submitted to the Administrator annually, as required by regulations prescribed by the Administrator.

3. 40 C.F.R. § 167.85(a) and (b) adds requirements for reporting: devices produced at registered pesticide-producing establishments; the name and address of the establishment; and an estimate of the amount of pesticide product to be produced during the current year.

4. 40 C.F.R. § 167.85(c), requires the producer to obtain, complete and submit

annually a pesticide reporting form supplied by EPA. The applicable form, “EPA Form 3540-16, *Pesticide Report for Pesticide-Producing and Device-Producing Establishments*” requires, *inter alia*, identification of the establishment; identification of the company; authorized signature and signature date; and specific pesticide production information. In addition, the “*Instructions for Completing EPA Form 3540-16 Pesticide Report for Pesticide-Producing and Device-Producing Establishments*” provides additional detail regarding information required on the Form.

5. 40 C.F.R. § 167.85(d) requires the pesticide-production reports to be filed annually on or before March 1, even if the producer has not produced any pesticidal products for that reporting year.

6. Respondent’s annual report for calendar year 2016 has not been submitted to EPA, as required by 40 C.F.R § 167.85(d).

7. Respondent’s annual report for calendar year 2017 has not been submitted to EPA, as required by 40 C.F.R § 167.85(d).

8. Respondent’s failure to comply with Section 7(c) of FIFRA and 40 C.F.R. § 167.85, constitutes a violation of Section 12(a)(2)(L) of FIFRA, 7 U.S.C. § 136j(a)(2)(L).

9. EPA and Respondent agree that settlement of this matter is in the public interest.

10. EPA is authorized to enter into this Expedited Settlement Agreement and Final Order (“Agreement”). Accordingly, this proceeding for the assessment of a civil penalty is simultaneously commenced and concluded, pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136l, and 40 C.F.R. § 22.13(b).

11. In signing this Agreement, Respondent: (a) admits that Respondent is subject to the requirements in Paragraphs 2 through 5 above; (b) admits that EPA has jurisdiction over

Respondent and Respondent's conduct as alleged herein; (c) neither admits nor denies the factual allegations contained herein; (d) consents to the assessment of this penalty; and (e) waives any right to contest the allegations contained herein, and its right to appeal the proposed Final Order set forth at page 6 of this Agreement.

12. Within 30 days of the effective date of this Agreement, Respondent shall pay a civil penalty of \$2,400.00 (two thousand and four hundred dollars and 00 cents) for the FIFRA violations identified in this Agreement by sending a cashier's or certified check, payable to "Treasurer, United States of America" via either:

- U.S. Mail to:

U.S. Environmental Protection Agency
P.O. Box 979077
St. Louis, MO 63197-9000

- Or overnight/common carrier (*i.e.*, FedEx, DHL, UPS) to:

U.S. Environmental Protection Agency
Government Lockbox 979077
1005 Convention Plaza SL-MO-C2-GL
St. Louis, MO 63101

Alternatively, the penalty payment to "Treasurer, United States of America" may be made via:

- Electronic deposit for payment (Vendor Express, Fedwire, Pay.gov) at <http://www2.epa.gov/financial/makepayment> following the online directions for an electronic funds transfer (EFT).

The check or electronic funds transfer instrument must state the case title ("In the Matter of: Coltene/Whaledent, Inc."), and the docket number of this Agreement.

13. When it pays the penalty, Respondent must send a notice of payment that states Respondent's name, complete address, and the case docket number (along with a photocopy of the check or a statement of affirmation or receipt of an electronic funds transfer) to:

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

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

14. Payment of the civil penalty shall resolve only Respondent's liability for federal civil penalties for the violations and facts alleged herein.

15. The civil penalty is not deductible for federal tax purposes.

16. If Respondent does not timely pay the civil penalty, EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties, and the United States' enforcement expenses for the collection action. The validity, amount and appropriateness of the civil penalties are not reviewable in a collection action.

17. EPA reserves all of its rights to take enforcement action for any other past, present, or future violations by Respondent of FIFRA, any other federal statute or regulation, or this Agreement.

18. Respondent certifies that it is complying with Section 7(c) of FIFRA, 7 U.S.C. § 136e(c), and its implementing regulations at 40 C.F.R. § 167.85.

19. Upon signing and returning this Agreement to EPA, Respondent waives any and all remedies, claims for relief and other available rights to judicial or administrative review that Respondent may have with respect to any issue of fact or law set forth in this Expedited Settlement Agreement, including the opportunity for a hearing or appeal pursuant to FIFRA and 40 C.F.R. Part 22 and any right of judicial review under Chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701 -706.

20. Each party shall bear its own costs and fees, if any.

21. The Agreement authorized by EPA's execution of the Final Order attached hereto constitutes a Final Order under 40 C.F.R. Part 22.

22. This Agreement is binding on the parties signing below, and in accordance with 40 C.F.R. § 22.31(b), is effective upon filing of the Final Order.

IT IS SO AGREED,

FOR RESPONDENT COLTENE/WHALEDENT, INC.:

Name (print): Nancy Spencer

Title (print): General Manager/Director of Operation

Signature: Nancy Spencer

Date 5/25/18

APPROVED BY EPA:

Michael D. Harris

Michael D. Harris
Acting Division Director
Land and Chemicals Division
United States Environmental Protection Agency
Region 5

Date 6/08/2018

In the Matter of: Coltene/Whaledent, Inc.

FINAL ORDER

Pursuant to authority of Section 14(a) of FIFRA, 7 U.S.C. § 136l, and 40 C.F.R. § 22.13(b), and according to the terms of this Agreement, IT IS HEREBY ORDERED THAT:

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

IT IS SO ORDERED:

Ann L. Coyle

Ann L. Coyle
Regional Judicial Officer
United States Environmental Protection Agency
Region 5

Date June 12, 2018

In the matter of: Coltene/Whaledent, Inc.
Docket Number: FIFRA-05-2018-0036

CERTIFICATE OF SERVICE

I certify that I served a true and correct copy of the foregoing **Expedited Settlement Agreement**, which was filed on, June 12, 2018 this day in the following manner to the addressees:

Copy by certified mail

Return-receipt requested:

Ms. Nancy Spencer
Director of Operations
Coltene/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, Ohio 44223

Copy by e-mail to

Attorney for Complainant:

Josh Zaharoff
zaharoff.josh@epa.gov

Copy by e-mail to

Regional Judicial Officer:

Ann Coyle
coyle.ann@epa.gov

Dated: June 12, 2018

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