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

DEC 07 2007

REPLY TO THE ATTENTION OF:
LC-8J

CERTIFIED MAIL
Receipt No. 7001 0320 0006 0185 7507

Rich Bulger
Mayer, Brown Rowe & Maw LLP
71 South Wacker Dr.
Chicago, IL 60606

Consent Agreement and Final Order, Docket No. **FIFRA-05-2008-0004**

Dear Mr. Bulger:

Enclosed pleased find a copy of a fully executed Consent Agreement and Final Order concerning violations of the Federal Insecticide Fungicide & Rodenticide Act (FIFRA), 7 §§ U.S.C.136 et seq., in resolution of the above case. This document was filed on December 7, 2007 with the Regional Hearing Clerk.

The civil penalty in the amount of $66,000 is to be paid in the manner prescribed in paragraphs 120 and 121. Please be certain that the number **BD 2750845P006** and the docket number are written on both the transmittal letter and on the check. Payment is due by January 7, 2008 (within 30 calendar days of the filing date).

Thank you for your cooperation in resolving this matter.

Sincerely,

Terence Bonace
Pesticides and Toxics Compliance Section

Enclosures

cc: Marcy Toney, Regional Judicial Officer/C-14J (w/Encl.)
Luis Oviedo, ORC/C-14J (w/Encl.)
Eric Volck, Cincinnati Finance/MWD (w/Encl.)

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	**Docket No. FIFRA-05-2008-0004**
	)	
Stepan Company	)	**Proceeding to Assess a Civil Penalty**
Northfield, Illinois,	)	**Under Section 14(a) of the Federal**
	)	**Insecticide, Fungicide, and Rodenticide**
Respondent.	)	**Act, 7 U.S.C. § 136*l*(a)**
	)	

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. § 136*l*(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 Land and Chemicals Division, United States Environmental Protection Agency (U.S. EPA), Region 5.

3. Respondent is Stepan Company, a corporation organized under the laws of the State of Illinois with a place of business at 22 West Frontage Road, Northfield, Illinois.

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. However, neither the entry of this CAFO nor anything contained therein shall constitute an admission of liability by Respondent.

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 that it is complying with FIFRA, 7 U.S.C. §§ 136 to 136y.

Statutory and Regulatory Background

10. Under 40 C.F.R. § 152.132, a registrant may distribute or sell his registered product under another person's name and address instead of his own if, *inter alia*, the registrant has submitted to U.S. EPA for each product a statement signed by both the registrant and the distributor listing the names and addresses of the registrant and the distributor, the distributor's company number, the additional brand names to be used, and the registration number of the product.

11. Under 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.

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

13. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(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.

14. Section 12(a)(1)(C) of FIFRA, 7 U.S.C. § 136(j)(a)(1)(C), states that it shall be unlawful for any person in any state to distribute or sell to any person any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under Section 3 of FIFRA, 7 U.S.C. § 136a.

15. "Distribute and 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 sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver."

16. A person is defined, in Section 2(s) of FIFRA, as meaning any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.

17. Section 2(t) of FIFRA, 7 U.S.C. § 136(t) defines a pest as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism.

18. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines the term "pesticide" as any

substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.

19. The Administrator of U.S. EPA may assess a civil penalty against any registrant who violates any provision of FIFRA of up to $5,500 for each offense that occurred from January 31, 1997 through March 15, 2004, and may assess a civil penalty of up to $6,500 for each offense that occurred after March 15, 2004, pursuant to Section 14(a)(l) of FIFRA, 7 U.S.C. § 136*l*(a)(l), and 40 C.F.R. Part 19.

Factual Allegations and Alleged Violations

20. On July 15, 2002, Wayne Toland, a U.S. EPA inspector, duly authorized to conduct inspections under FIFRA, conducted an inspection at *Swish Maintentance, LTD*, 703 Pine Street, Burlington, Vermont, in order to examine and collect samples of pesticides packaged, labeled, and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

21. During the July 15, 2002 inspection, inspector Toland collected samples of **Enviro Solutions 25 Disinfectant Cleaner and Deodorizer**, EPA Reg. No. 1839-101-68138. **Enviro Solutions 25 Disinfectant Cleaner and Deodorizer** is a "pesticide" as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

22. On September 5, 2002, Gwen Minton, an inspector with the North Carolina Department of Agriculture and Consumer Services, duly authorized to conduct inspections under FIFRA, conducted an inspection at *Handi-Clean Products, Inc.*, 301 Swing Road, Greensboro,

North Carolina, in order to examine and collect samples of pesticides packaged, labeled, and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

23. During the September 5, 2002 inspection, inspector Minton collected samples of **Control Detergent Disinfectant**, EPA Reg. No. 1839-81-10320.

24. **Control Detergent Disinfectant** is a "pesticide" as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

25. On September 11, 2002, William Townsell, an inspector with the Tennessee Department of Agriculture, duly authorized to conduct inspections under FIFRA, conducted an inspection at *Hanco Manufacturing Company*, 1301 Heistan Place, Memphis, Tennessee, in order to examine and collect samples of pesticides packaged, labeled, and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

26. During the September 11, 2002 inspection, inspector Townsell collected a sample of **Hanco 900 Lemon Kleen**, EPA Reg. No. 1839-102-9931.

27. **Hanco 900 Lemon Kleen** is a "pesticide" as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

28. On October 21 and 25, 2002, Nancy Harris, an inspector with the Michigan Department of Agriculture, duly authorized to conduct inspections under FIFRA, conducted an inspection at *Arrow Chemical Products, Inc.*, 2067 Saint Avenue, Detroit, Michigan, in order to examine and collect samples of pesticides packaged, labeled, and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

29. During the October 21 and 25, 2002 inspections, inspector Harris collected a sample

of **Super-M Sanitizer**, EPA Reg. No. 1839-47-5747.

30. During the October 21 and 25, 2002 inspections, inspector Harris also collected samples of **Arrow Sanitizer**, EPA Reg. No. 1839-86-5747.

31. During the October 21 and 25, 2002 inspections, inspector Harris also collected samples of **Mint Quaternary Disinfectant Cleaner**, EPA Reg. No. 1839-101-5747.

32. During the October 21 and 25, 2002 inspections, inspector Harris also collected samples of **Pine Quaternary Disinfectant Cleaner**, EPA Reg. No. 1839-103-5747.

33. **Super- M Sanitizer**, **Arrow Sanitizer**, **Mint Quaternary Disinfectant Cleaner**, and **Pine Quaternary Disinfectant Cleaner** are "pesticides" as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

34. On December 3, 2002, Leo Reed, an inspector with the Office of Indiana State Chemist, duly authorized to conduct inspections under FIFRA, conducted an inspection at *Warsaw Chemical Company, Inc.*, P.O. Box 858, Warsaw, Indiana, in order to examine and collect samples of pesticides packaged, labeled, and released for shipment, as authorized under Section 9 of FIFRA, 7 U.S.C. § 136g.

35. During the December 3, 2002 inspection, inspector Reed collected a sample of **TB Quat**, EPA Reg. No. 1839-83-2230.

36. **TB Quat** is a "pesticide" as that term is defined at Section 2(u) of FIFRA, 7 U.S.C. § 136(u).

37. On or about August 10, 1994, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Enviro Solutions LTD and Respondent.

38. The Form identifies Respondent as the basic registrant of **CD 1.6 (D & F) Detergent Disinfectant** (EPA Reg. No. 1839-101), the basic registered product, and Enviro Solutions LTD as the distributor company, whose distributor brand product name is **Enviro Solutions 25 Disinfectant Cleaner and Deodorizer**.

39. On or about June 2, 1989, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Handi-Clean Products, Inc. and Respondent.

40. The Form identifies Respondent as the basic registrant of **NP 9.0 Detergent/Disinfectant** (EPA Reg. No. 1839-81), the basic registered product, and Handi-Clean Products, Inc. as the distributor company, whose distributor brand product name is **Control Detergent/Disinfectant**.

41. On or about June 11, 1985, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Hanco Manufacturing Company and Respondent.

42. The Form identifies Respondent as the basic registrant of **CD 4.5 (D & F)** (EPA Reg. No. 1839-102), the basic registered product, and Hanco Manufacturing Company as the distributor company, whose distributor brand product name is **Hanco 900 Lemon Kleen**.

43. On or about July 31, 1989, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Arrow Chemical Products, Inc. and Respondent.

44. The Form identifies Respondent as the basic registrant of **CD 4.5**

Detergent/Disinfectant (EPA Reg. No. 1839-47), the basic registered product, and Arrow Chemical Products, Inc. as the distributor company, whose distributor brand product name is **Super-M-Sanitizer**.

45. On or about July 31, 1989, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Arrow Chemical Products, Inc. and Respondent.

46. The Form identifies Respondent as the basic registrant of **BTC 2125 M 10% Solution** (EPA Reg. No. 1839-86), the basic registered product, and Arrow Chemical Products, Inc. as the distributor company, whose distributor brand product name is **Arrow Sanitizer**.

47. On or about September 28, 1981, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Arrow Chemical Products, Inc. and Respondent.

48. The Form identifies Respondent as the basic registrant of **CD 1.6 (D & F) Detergent/Disinfectant** (EPA Reg. No. 1839-101), the basic registered product, and Arrow Chemical Products, Inc. as the distributor company, whose distributor brand product name is **Mint Quaternary Disinfectant Cleaner**.

49. On or about September 8, 1993, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form) to U.S. EPA, signed by representatives of Arrow Chemical Products, Inc. and Respondent.

50. The Form identifies Respondent as the basic registrant of **CD 3.2 (D & F)**

Detergent/Disinfectant (EPA Reg. No. 1839-103), the basic registered products, and Arrow Chemical Products, Inc. as the distributor company, whose distributor brand product name is **Pine Quaternary Disinfectant Cleaner**.

51. On or about April 23, 1996, Respondent submitted a "Notice of Supplemental Registration of Distributor," EPA Form 8570-5 (Form), to U.S. EPA, signed by representatives of Warsaw Chemical Company, Inc. and Respondent.

52. The Form identifies Respondent as the basic registrant of **Detergent Disinfectant Pump Spray** (EPA Reg. No. 1839-83), the basic registered product, and Warsaw Chemical Company, Inc. as the distributor company, whose distributor brand product name is **TB Quat**.

53. Respondent is a "person" as that term is defined in Section 2(s) of FIFRA, 7 U.S.C. § 136(s).

54. Respondent "distributed or sold" the pesticides identified in 23, 26, 29, 32, 33, 34, 35 and 38, as that term is defined in Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), in that the pesticides collected by the inspectors were from pesticides packaged, labeled, and released for shipment or sale by Respondent's agents.

COUNT I

55. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

56. The label of Respondent's agent's pesticide, **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer,** states, among other things, that "When diluted at the rate of 4.5 ounces per gallon of water, Enviro Solutions 25 Disinfectant Cleaner & Deodorizer exhibits effective disinfection activity against the organisms Salmonella choleraesuis, Staphylococcus aureus and

Escherischia coli." and "Efficacy tests have demonstrated that **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** is an effective bactericide and fungicide in the presence of organic soil (5% blood serum)."

57. Samples of **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** collected during the July 15, 2002 inspection at Swish Maintenance, LTD, were analyzed by the U.S. EPA OPP Microbiology Laboratory in Fort Meade, Maryland, for efficacy against the microorganism *Staphylococcus aureus*.

58. Efficacy data results from this analysis revealed that **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** as ineffective against *Staphylococcus aureus*, when tested by A.O.A.C. Use Dilution Test Method at a 6:128 dilution in sterile, deionized water, in the presence of 5%horse serum, for a contact time of 10 minutes at 20°C.

59. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Staphylococcus aureus*.

60. The sale and distribution of the misbranded pesticide **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT II

61. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

62. Section 12(a)(1)(C) of FIFRA, 7 U.S.C.§ 136j(a)(1)(C) states that it is unlawful to

distribute or sell any registered pesticide whose composition differs at the time of distribution or sale from its composition as described in the statement required in connection with its registration under Section 3 of FIFRA, 7 U.S.C. § 136a.

63. The statement of formulation of **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** states that the product contains 0.80% of alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides and 0.80% of alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides, which is a total of 1.6% quaternary ammonium.

64. Analysis of the sample collected on July 15, 2002, and performed by the Analytical Chemistry Branch of the U.S. EPA in Fort Meade, Maryland, revealed that the pesticide **Enviro Solutions 25 Disinfectant Cleaner & Deodorizer** contained 1.74% total quaternary ammonium.

65. Respondent's distribution or sale of **Enviro Solutions 25 Disinfectant Cleaner & Deodorize,** whose composition was 8.8% greater than the composition in its statement of formula, constitutes an unlawful act pursuant to Section 12(a)(1)(C) of FIFRA, 7 U.S.C. § 136j(a)(1)(C).

COUNT III

66. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

67. The label of Respondent's agent's pesticide **Control Detergent/Disinfectant** states, among other things, that "When diluted at the rate of 1 ounce per gallon of water, Control Detergent/Disinfectant exhibits disinfectant activity against the organisms Psuedomonas aeruginosa . . . ." and " Efficacy tests have demonstrated that Control Detergent/Disinfectant is

an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum)."

68. A sample of **Control Detergent/Disinfectant** collected during the September 5, 2002 inspection at Handi-Clean Products, Inc. was analyzed by the U.S. EPA OPP Microbiology Laboratory in Fort Meade, Maryland, for efficacy against the microorganism *Pseudomonas aeruginosa*.

69. Efficacy data results from this analysis revealed that **Control Detergent/Disinfectant** is ineffective against *Pseudomonas aeruginosa*, when tested by A.O.A.C. Use Dilution Test Method at a 1:128 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

70. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa*.

71. The sale and distribution of the misbranded pesticide **Control Detergent/Disinfectant** constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT IV

72. Complainant incorporates by reference the allegations contained by paragraphs 1 through 56 of the Complaint.

73. The label of Respondent's agent's pesticide **Hanco 900 Lemon Kleen** states, among other things, "Pseudomonas aeruginosa," that **Hanco 900 Lemon Kleen** "when diluted at a rate of 2 ounces per gallon of water is an effective disinfectant against the organisms Pseudomonas aeruginosa . . . ." and "Efficacy tests have demonstrated that **Hanco 900 Lemon**

Kleen is an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum)."

74. A sample of **Hanco 900 Lemon Kleen** collected during the September 11, 2002 inspection at Hanco Manufacturing Company was analyzed by the North Carolina Department of Agriculture Microbiology Laboratory for efficacy against the microorganism *Pseudomonas aeruginosa*.

75. Efficacy data results from this analysis revealed that **Hanco 900 Lemon Kleen** is ineffective against *Pseudomonas aeruginosa*, when tested by A.O.A.C. Use Dilution Test Method at a 1:64 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

76. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa*.

77. The sale and distribution of the misbranded pesticide **Hanco 900 Lemon Kleen** constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT V

78. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

79. The label of Respondent's agent's pesticide **Super-M Sanitizer** states, among other things, "Pseudomonas aeruginosa" and "when diluted at a rate of 3 ounces per gallon of water, this product exhibits effective disinfectant activity against Pseudomonas aeruginosa . . . and meets all requirements for hospital use" and "Efficacy tests have demonstrated that this product

is an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum)."

80. The label submitted for registration of **CD 4.5 Detergent/Disinfectant** by Respondent states, "when diluted at a rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against Pseudomonas aeruginosa . . . and meets all requirements for hospital use" and "Efficacy tests have demonstrated that this product is an effective bactericide, fungicide and virucide in the presence of organic soil (5% blood serum)."

81. A sample of **Super-M Sanitizer** collected during the October 21 and 25, 2002 inspections at Arrow Chemical Products, Inc. was analyzed by the U.S. EPA OPP Microbiology Laboratory in Ft. Meade, Maryland for efficacy against the microorganism *Pseudomonas aeruginosa*.

82. Efficacy data results from this analysis revealed that **Super-M Sanitizer** is ineffective against *Pseudomonas aeruginosa*, when tested by A.O.A.C. Use Dilution Test Method at a 1:64 dilution (as on the label submitted for registration) in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

83. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa*.

84. The sale and distribution of the misbranded pesticide **Super-M Sanitizer** constitutes an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT VI

85. Complainant incorporates by reference the allegations contained by paragraphs 1

through 54 of the Complaint.

86. The label of Respondent's agent's pesticide **Arrow Sanitizer** states, among other things, "Hospital Disinfection: Add 3 ½ ounces of the product per 5 gallons of water for disinfection against Pseudomonas aeruginosa . . . ." and "Efficacy tests have demonstrated that this product is an effective bactericide and virucide in the presence of organic soil (5% blood serum)."

87. Samples of **Arrow Sanitizer** collected during the October 21 and 25, 2002 inspections at Arrow Chemical Products, Inc. were analyzed by the U.S. EPA OPP Microbiology Laboratory in Ft. Meade, Maryland for efficacy against the microorganism *Pseudomonas aeruginosa*.

88. Efficacy data results from this analysis revealed that **Arrow Sanitizer** are ineffective against *Pseudomonas aeruginosa*, when tested by A.O.A.C. Use Dilution Test Method at a 3.5:640 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

89. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa*.

90. The sale and distribution of the missbranded pesticide **Arrow Sanitizer** constitutes an unlawful acts pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT VII

91. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

92. The label of Respondent's agent's pesticide **Mint Quaternary Disinfectant Cleaner** states, among other things, that "When diluted at a rate of 6 ounces per gallon of water, the product exhibits disinfectant activity against Pseudomonas aeruginosa . . . ." and "Efficacy tests have demonstrated that this product is an effective bactericide and fungicide in the presence of organic soil (5% blood serum)."

93. Samples of **Mint Quaternary Disinfectant Cleaner** collected during the October 2 and 25, 2002 inspections at Arrow Chemical Products, Inc. were analyzed by the U.S. EPA OPP Microbiology Laboratory in Ft. Meade, Maryland for efficacy against the microorganism *Pseudomonas aeruginosa*.

94. Efficacy data results from this analysis revealed that **Mint Quaternary Disinfectant Cleaner** was ineffective against *Pseudomonas aeruginosa*, when tested by A.O.A.C. Use Dilution Test Method at a 6:128 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

95. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa*.

96. The sale and distribution of the misbranded pesticide **Mint Quaternary Disinfectant Cleaner** constitute an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT VIII

97. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

98. The statement of formulation of **Mint Quaternary Disinfectant Cleaner** states that the product contains 0.80% of alkyl (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) dimethyl benzyl ammonium chlorides and 0.80% of alkyl (68% C_{12}, 32% C_{14}) dimethyl ethylbenzyl ammonium chlorides, which is a total of 1.6% quaternary ammonium.

99. Analysis of the samples collected during the October 21 and 25, 2002 inspections was performed by the Analytical Chemistry Branch of the U.S. EPA in Fort Meade, Maryland. This analysis revealed that the pesticide **Mint Quaternary Disinfectant Cleaner** contained 2.04% total quaternary ammonium in lot 25207192, 2.04% total quaternary ammonium in lot 25208132, and 1.82% total quaternary ammonium in lot 25210102.

100. Respondent's distribution or sale of pesticide **Mint Quaternary Disinfectant Cleaner,** whose compositions were, respectively, 27.5%, 27.5% and 13.8%, greater than the composition in the product's statement of formula, constitutes an unlawful act pursuant to Section 12(a)(1)(C) of FIFRA, 7 U.S.C. § 136j(a)(1)(C).

COUNT IX

101. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

102. The label of Respondent's agent's pesticide **Pine Quaternary Disinfectant Cleaner** states, among other things, that "Bactericidal Activity: When diluted at a rate of 2 ounces per gallon of water, this product exhibits effective disinfectant activity against the organisms: Salmonella choleraesuis and Staphylococcus aureus. When diluted at the rate of 3 ounces per gallon of water, this product exhibits disinfectant activity against Pseudomonas aeruginosa in addition to the above mentioned microorganisms and meets all requirements for

hospital use." and "Efficacy tests have demonstrated that this product is an effective bactericide and fungicide in the presence of organic soil (5% blood serum)."

103. Samples of **Pine Quaternary Disinfectant Cleaner**, collected during the October 21 and 25, 2002 inspections at Arrow Chemical Products, Inc. were analyzed by the U.S. EPA OPP Microbiology Laboratory in Ft. Meade, Maryland for efficacy against the microorganisms *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

104. Efficacy data results from this analysis revealed that one lot of **Pine Quaternary Disinfectant Cleaner** was ineffective against *Staphylococcus aureus* when tested by A.O.A.C. Use Dilution Test Method at a 3:128 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

105. Efficacy data results from this analysis revealed that the samples of **Pine Quaternary Disinfectant Cleaner** were ineffective against *Psuedomonas aeruginosa* and *Staphylococcus aureus* when tested by A.O.A.C. Use Dilution Test Method at a 3:128 dilution in sterile, deionized water, in the presence of 5 percent horse serum, for a contact time of 10 minutes at 20 degrees C.

106. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa* and *Staphylococcus aureus*.

107. The sale and distribution of the misbranded pesticide **Pine Quaternary Disinfectant Cleaner** constitute an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

COUNT X

108. Complainant incorporates by reference the allegations contained in paragraphs 1

through 54 of this Complaint.

109. The label of Respondent's agent's pesticide **TB Quat,** states, among other things, that the product contains .105% n-alkyl dimethyl benzyl ammonium chlorides (60% C_{14}, 30% C_{16}, 5% C_{12}, 5% C_{18}) and .105% n-alkyl dimethyl ethylbenzyl ammonium chlorides (68% C_{12}, 32% C_{14}), which has the quaternary nitrogen equivalent of .008%.

110. Analysis of the above sample performed by the Office of the Indiana State Chemist revealed that **TB Quat** contained .013% quaternary nitrogen equivalent.

111. Respondent's distribution or sale of the pesticide **TB Quat**, whose composition was 62.5% greater than the composition in its statement of formula, constitutes an unlawful act pursuant to Section 12(a)(1)(C) of FIFRA, 7 U.S.C.§ 136j(a)(1)(C).

COUNT XI

112. Complainant incorporates by reference the allegations contained by paragraphs 1 through 54 of the Complaint.

113. The label of Respondent's agent's pesticide **DeVere QD II Quaternary Disinfectant**, states, among other things, "HOSPITAL DISINFECTION-Add 3.5 ounces of this product per 5 gallons of water to disinfect against Psuedomonas aeruginaosa" and "Efficacy tests have demonstrated that this product is an effective bactericide and fungicide in the presence of organic soil (5% blood serum)."

114. A sample of **DeVere QD II Quaternary Disinfectant**, collected during the October 22, 2004 inspection at DeVere Company, Inc. was analyzed by the U.S. EPA OPP Microbiology Laboratory in Ft. Meade, Maryland for efficacy against the microorganism *Pseudomonas aeruginosa.*

115. Efficacy data results from this analysis revealed that **DeVere QD II Quaternary Disinfectant** was ineffective against *Pseudomonas aeruginosa* when tested by A.O.A.C. Use Dilution Test Method at a 3.5:636.5 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20 °C.

116. Efficacy data results from this analysis revealed that **DeVere QD II Quaternary Disinfectant** was ineffective against *Psuedomonas aeruginosa* when tested by A.O.A.C. Use Dilution Test Method at a 3.5:636.5 dilution in sterile, deionized water, in the presence of 5% horse serum, for a contact time of 10 minutes at 20°C.

117. Respondent's agent's label is false and misleading in its claim of antimicrobial efficacy against *Psuedomonas aeruginosa.*

118. Respondent's sale and distribution of pesticide **DeVere QD II Quaternary Disinfectant** constitute an unlawful act pursuant to Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E).

Civil Penalty

119. Pursuant to Section 14(a)(4) of FIFRA, 7 U.S.C. § 136*l*(a)(4), Complainant determined that an appropriate civil penalty to settle this action is $ 111,000.00. In determining the penalty amount, Complainant considered the appropriateness of the penalty to the size of Respondent's business, the effect on Respondent's ability to continue in business, and the gravity of the violation. Complainant also considered U.S. EPA's *Enforcement Response Policy for the Federal Insecticide, Fungicide, and Rodenticide Act,* dated July 2, 1990 [or] U.S. EPA's *Enforcement Response Policy for FIFRA Section 7(c) Pesticide Producing Establishment Reporting Requirement*, dated February 10, 1986. Complainant has determined that there was no

economic benefit associated with the alleged violations. Therefore, Complainant has determined that the appropriate penalty to settle this action is $66,000.00.

120. Within 30 days after the effective date of this CAFO, Respondent must pay a $ 66,000.00 civil penalty for the FIFRA violations. Respondent must pay the penalty by sending a cashier's or certified check, payable to the "Treasurer, United States of America," to:

U.S. EPA, Region 5
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

The check must note the following: case title, the docket number of this CAFO and the billing document number.

121. A transmittal letter, stating, Respondent's name, the case title, Respondent's complete address, the case docket number and the billing document number must accompany the payment. Respondent must send a copy of the check and transmittal letter to:

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

Terence Bonace (LC-8J)
Land and Chemicals Division
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Luis Oviedo (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

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

123. If Respondent does not pay the civil penalty timely, U.S. 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. § 136*l*(a)(5). The validity, amount and appropriateness of the civil penalty are not reviewable in a collection action.

124. 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.

125. This CAFO is conditional upon Respondent's completion of the attached "Self-Audit Plan" (Attachment A), and all of its terms and conditions, incorporated herein by reference as if fully set forth in this CAFO.

126. The timeframes, benchmarks and completion deadlines of the Self-Audit Plan are hereby incorporated by reference as if fully set forth in this CAFO. If any event occurs which causes delays in the completion of activities set forth in the Self-Audit Plan, Respondent shall notify U.S. EPA in writing not more than twenty-one (21) days after the delay or Respondent's knowledge of the delay. The notice shall describe in detail the anticipated length of the delay, the precise cause or causes of the delay, the measures taken and to be taken by Respondent to prevent or minimize the delay, and the timetable by which those measures will be implemented. The Respondent shall adopt reasonable measures to avoid or minimize any such delay. If the delay has been reasonably caused by circumstances beyond the control of Respondent, the time

for performance hereunder may be extended for a period no longer than the delay resulting from such circumstances.

General Provisions

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

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

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

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

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

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

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

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

Stepan Company, Respondent

11/9/07

Date

David Shelton, Senior Manager
Anti-Microbial Product Development

United States Environmental Protection Agency, Complainant

11/28/07

Date

Margaret M. Guerriero, Director
Land and Chemicals Division

FIFRA-05-2008-0004

In the Matter of:
Stepan Company
Docket No. FIFRA-05-2008-0004

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.

12-4-07
Date

Mary A. Gade
Regional Administrator
United States Environmental Protection Agency
Region 5

Attachment A

Stepan Company Protocol for Biocide Formulator and Subregistrant Audit Program

1.0 Objective

To provide detailed plans for auditing formulators and subregistrants of Stepan biocides.

2.0 Qualifications of Auditors

All Stepan auditors will have the following qualifications:

College degree in one or more sciences (i.e., chemistry, biology, etc.)
At least one year of relevant industry experience.
Good Laboratory Practices (GLP) training which is updated every two years.

3.0 Training of Auditors

All Stepan auditors will have successfully completed "auditor training" as offered by the Stepan manufacturing division within 12 months of assuming auditor duties.

4.0 Schedule and Timeframe for Audits

1 month from approval of program:	Communication of the audit program to internal sales, marketing, and general management.
+ 3 months from approval:	Initial correspondence to all Stepan subregistrants and formulators (approx. 3700 customers) reminding them of their legal obligations as formulators and subregistrants of Stepan biocides.
+ 4 months from approval:	Send correspondence to 100 customers (formulators and subregistrants) requiring them to complete the self-audit and return it to Stepan.
+ 5 months from approval:	Send correspondence to the next 100 customers requiring them to complete the self-audit and return it to Stepan. Review responses from + 4 months from approval correspondence.

	Follow-up with customers that provide negative answers, outdated CSFs, outdated or incorrect labels, or incomplete responses.
	Follow-up with customers that do not respond to audit request.
	Identify customer for on-site audit.
	Scan all self-audits into a searchable electronic database.
+ 6 months from approval:	Send correspondence to the next 100 customers requiring them to complete the self-audit and return it to Stepan.
	Review responses from + 5 months from approval correspondence.
	Follow-up with customers that provide negative answers.
	Follow-up with customers that do not respond to audit request.
	Identify customer for next on-site audit.
	Analyze retain sample(s) from previous on-site audit.
	Scan all self-audits into a searchable electronic database.
+ 6 months from approval:	Repeat + 6 months from approval activities, reflecting the correct month.

⬇↓
December 2010

5.0 Process to Target On-Site Audits

If Stepan becomes aware of a product efficacy or product composition failure, then the customer that formulated the product will be subject to an on-site audit within 30 days of Stepan receiving such information. *Product efficacy and composition failures will be our highest priority for on-site audits.*

If there are no efficacy or composition failures for a given month, then the audit will be based on objectionable responses to the self-audit.

If there are no product efficacy or composition failures and if there are no objectionable responses to any self-audit questions, then a customer will be chosen at random for on-site audit retaining a policy of one audit per month.

6.0 Periodic Audit Reports

An audit report will be made available to EPA and Stepan management on a yearly basis, starting in December, 2007. The report will consist of: (1) companies that were required to do self-audit, (2) companies that were required to participate in on-site audit, (3) companies that compiled with our request, and (4) audit results.

7.0 Retain Samples

A % quaternary chloride analysis will be done on all retain samples received by Stepan. This data will be part of the permanent record for the on-site audit. This data will also be made available as part of the yearly report to EPA and Stepan management.

The % quaternary analysis result for any given product will be compared to the concentration limits on the Confidential Statement of Formula (CSF). If our analytical results are outside the CSF limits then the formulator will be subject to re-audit within 12 months of the analysis date.

8.0 Appendices

No.	Title
1	Biocide Formulator Onsite Audit
2	Formulator Self-Audit
3	Subregistrant Self-Audit

SUBREGISTRANT SELF-AUDIT

Subregistrant's Company Name: _____
Subregistrant's Address: _____
Subregistrant's EPA#: _____
Stepan Product(s) Subregistered: _____
Audit Date: _____
Auditor: _____
Auditor's Phone #: _____
Auditor's Title And Position: _____

1. Do you have a subregistrant licensing agreement signed by yourself and Stepan?

   Yes ☐ No ☐

   Additional Comments:

2. Do you have an EPA Supplemental Registration Form (EPA Form#8570-5) signed by yourself and Stepan for each product you subregister from Stepan?

   Yes ☐ No ☐

   Additional Comments:

3. Are you registered in the states where you are currently marketing/distributing Stepan subregistered product?

   Yes ☐ No ☐

   Additional Comments:

4. Please list the products you subregister from Stepan by EPA registration number.

   _____ _____

   _____ _____

   _____ _____

7.18.06 (Revised 12.14.06) DS/BEG0169

FORMULATOR SELF-AUDIT

Formulator's Company Name: _____
Formulator's Address: _____
EPA Establishment Number: _____
Stepan Product(s) Manufactured: _____
Audit Date: _____
Auditor: _____
Auditor's Phone #: _____
Auditor's Title and Position: _____

1. Do you have a current Stepan "Confidential Statement of Formula" (CSF) for each Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

2. Do you have a current Stepan manufacturing procedure for each Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

3. Do you follow the current Stepan manufacturing procedure for each Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

4. Do "batch tickets" exist for each batch of Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

Please send a copy of the last three completed "batch tickets" for each Stepan subregistered product that you manufacture.

5. Do you have finished product specifications for each Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

6. Do analytical methods exist for product specifications related to each Stepan subregistered product you manufacture?

   Yes ☐ No ☐

   Additional Comments:

7. Do finished product retains exist for each batch of Stepan subregistered product that you manufacture?

   Yes ☐ No ☐

   Additional Comments:

8. Please send a copy of the current label for each Stepan subregistered product that you manufacture.

9. Please indicate the date for each Stepan Confidential Statement of Formula (CSF) that you currently have.

Formulator's Company Name: _____
EPA Establishment Number: _____
Stepan Product Manufactured: _____
Audit Date: _____
Auditor: _____
Auditor's Title And Position: _____

MINIMUM GUIDELINES FOR BIOCIDE FORMULATOR ONSITE AUDIT

	Responses
Does customer have a current Stepan CSF?	
Does customer have a current Stepan manufacturing procedure?	
Do raw materials used in product conform to CSF?	
Do raw material suppliers conform to CSF?	
Are there specifications for incoming raw materials?	
Are raw material non-conformances documented?	
What is the procedure if a raw material is not in spec?	
Are raw materials warehoused under recommended conditions?	
Are suppliers notified of all non-conformances?	
Is the Stepan manufacturing (mfr.) procedure being followed?	
When was the last time the mfr procedure was reviewed?	
How do you ensure that the correct amount of each ingredient is added to each batch?	
Are there any "upsets" during production?	
Does the finished product always meet mfr specs?	
Do you have quality plans to re-blend material?	
Are mfr reactors and piping made of recommended materials?	
Do procedures exist for how and how often to clean batch reactors?	
Do "batch tickets" exist for each product batch? --examine examples of batch tickets	
Does a product sampling procedure exist?	
Is the sampling procedure being followed?	
Do batch retains exist for each batch?	
How are the retains stored and for how long?	
Is there a sample disposal procedure?	
Is the procedure being followed?	
Are storage tanks labeled properly?	
Are storage tanks and piping made of recommended materials?	
Do procedures exist for how and how often to clean storage tanks?	
Are the procedures being followed?	

	Responses
Review final product specs.	
Do Analytical methods exist for each product spec?	
Do procedures exist for analytical equipment maintenance?	
Are the procedures being followed?	
Is there a calibration schedule for analytical equipment?	
Is the schedule being adhered to?	
Are analytical reagents "standardized"?	
Do all reagents meet shelf-life dates?	
Are analytical personnel trained and is it documented?	
Do finished product retains exist for each production lot?	
How are retains stored?	
Examine examples of finished product retains?	
Do procedures exist for warehousing finished product?	
Are the procedures being followed?	
How is product transported from the mfr to the customer?	
Do you send your annual production volume of disinfectants to EPA?	
Do you send your annual production volume of disinfectants to state government agencies?	

Retain Sample: Please send 100 ml of a retain sample for each Stepan product you produce. Please indicate the production lot# on the sample bottle.

Label: Please send a current label for each Stepan product you produce.

Analysis of Retain Sample(s)

Batch Identification Code	% Quat Active	pH

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 Stepan Company, was filed on December 7, 2007 with the Regional Hearing Clerk (E-13J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, and that I mailed by Certified Mail, Receipt No. 7001 0320 0006 0185 7507, a copy of the original to the Respondent's Attorney:

Rich Bulger
Mayer, Brown Rowe & Maw LLP
71 South Wacker Dr.
Chicago, IL 60606

and forwarded copies (intra-Agency) to:

Marcy Toney, Regional Judicial Officer, ORC/C-14J
Luis Oviedo, Counsel for Complainant/C-14J
Eric Volck, Cincinnati Finance/MWD

Elizabeth Lytle

Elizabeth Lytle
Pesticides and Toxics Compliance Section
U.S. EPA - Region 5
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

Docket No. **FIFRA-05-2008-0004**

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