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

BEFORE THE ADMINISTRATOR

In the Matter of:)	
Danolyte Global, Inc.)	Docket No. FIFRA-07-2020-0185
	Respondent)	

CONSENT AGREEMENT AND FINAL ORDER

Preliminary Statement

The U.S. Environmental Protection Agency, Region 7 (EPA or Complainant), and Danolyte Global, Inc. ("Danolyte") have agreed to a settlement of this action before the 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 and the Revocation/Termination or Suspension of Permits, 40 C.F.R. §§ 22.13(b) and 22.18(b)(2).

Jurisdiction

- 1. This proceeding is an administrative action for the assessment of civil penalties initiated pursuant to Section 14 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136*l*.
- 2. This Consent Agreement and Final Order serves as notice that EPA has reason to believe that Respondent has violated Section 12 of FIFRA, 7 U.S.C. § 136j.

Parties

- 3. Complainant, by delegation from the Administrator of EPA, the Regional Administrator of Region 7, and the Director of the Enforcement and Compliance Assurance Division, Region 7, is the Branch Chief of the Chemical Branch, EPA, Region 7.
- 4. Respondent is a corporation in good standing under the laws of the state of Kansas.

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 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it shall be unlawful for any person to distribute or sell any pesticide that is adulterated or misbranded.
- 7. Section 12(a)(1)(F) of FIFRA, 7 U.S.C. §136j(a)(1)(F), states that it shall be unlawful for any person to distribute or sell any device which is misbranded.
- 8. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines "pesticide" to mean any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.
- 9. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines "person" to mean any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not.
- 10. Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), defines "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.
- 11. Section 2(h) of FIFRA, 7 U.S.C. §136(h) defines "device" as any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the applications of pesticides when sold separately therefrom.
- 12. Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and 40 C.F.R. § 167.3 define "produce" as meaning to manufacture, prepare, propagate, compound, or process any pesticide or device or active ingredient or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.
- 13. Section 2(w) of FIFRA, 7 U.S.C. § 136(w), and 40 C.F.R. § 167.3 define "producer" to mean any person who manufactures, prepares, compounds, propagates or processes any pesticide or device or active ingredient used in producing a pesticide (such actions include packaging, repackaging, labeling, and relabeling a pesticide).
- 14. Section 2(p) of FIFRA, 7 U.S.C. §136(p), in pertinent part, defines "label and labeling" to mean all labels and 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 except to current official publications....

- 15. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), states, in pertinent part, that a pesticide is misbranded if its labeling bears any statement which is false or misleading in any particular.
- 16. Section 2(q)(1)(F) of FIFRA, 7 U.S.C. §136(a)(1)(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 136a(d) of this title, are adequate to protect health and the environment.
- 17. Section 2(q)(1)(E) of FIFRA, 7 U.S.C. § 136(q)(1)(E), states that a pesticide is misbranded if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- 18. Section 2(q)(2)(C)(i) of FIFRA, 7 U.S.C. § 136(q)(2)(C)(i), states that a pesticide is mislabeled if there is not affixed to the container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing the name and address of the producer, registrant or person for whom produced.
- 19. Section 2(q)(2)(C)(ii) of FIFRA, 7 U.S.C. § 136(q)(2)(C)(ii), states that a pesticide is mislabeled if there is not affixed to the container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing the name, brand, or trademark under which the pesticide is sold.
- 20. Pursuant to 40 C.F.R. § 152.500(b), device is subject to the requirements set forth in, inter alia, FIFRA Section 2(q)(1) and 40 C.F.R. Part 156, with respect to labeling.
- 21. Section 14(a)(1) of FIFRA, 7 U.S.C. § 136*l*(a)(1), authorizes a civil penalty of not more than \$5,000 for each offense. The Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, as amended, and the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. § 2461, and implementing regulations at 40 C.F.R. Part 19, increased these statutory maximum penalties to \$7,500 for violations that occurred before November 2, 2015, and to \$20,288 for violations that occur after November 2, 2015, and for which penalties are assessed on or after January 13, 2020.

General Factual Allegations

22. Respondent is, and at all times referred to herein was, a "person" within the meaning of FIFRA. Respondent is a supplemental distributor of the pesticide *Excelyte Vet* (EPA Registration Number 92108-1) using the brand name *Danolyte* (EPA Registration Number 92108-1-91582).

- 23. Respondent manufactures and distributes a machine called *Danolyte Just in Time* 300 (DJIT 300), which uses inputs of water, salt, and hydrochloric acid to produce hypochlorous acid. The product produced by the DJIT 300 is an EPA Registered Pesticide (*Excelyte Vet/Danolyte*). The machine is a device under Section 2(h) of FIFRA, 7 U.S.C. § 136(h).
- 24. On February 27, 2019, the Kansas Department of Agriculture conducted a neutral scheme Producer Establishment Inspection on behalf of the Environmental Protection Agency at the Danolyte Global facility located at 9216 Bond Street in Overland Park, Kansas.
- 25. Upon the request of EPA, KDA performed a follow-up inspection on June 11, 2019. Both inspections collected pictures of the DJIT 300 and *Danolyte* products.
- 26. On October 29, 2019, EPA sent a request for information to Respondent requesting some additional information related to both the DJIT 300 and *Danolyte*. EPA received a response from Respondent on November 7, 2019.

Allegations of Violations

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

Count 1 – Misbranding the DJIT 300 Device

The facts stated in Paragraphs 1 through 22 above are herein incorporated.

- 28. 40 C.F.R. § 156.10(a)(1) states that every pesticide product shall bear a label containing the information specified by FIFRA and regulations in 40 C.F.R. Part 156.
- 29. 40 C.F.R. § 156.10(a)(1)(vii) states that the label shall clearly and prominently display hazard and precautionary statements as prescribed in Subpart D of 40 C.F.R. Part 156 for human and domestic animal hazards, and subpart E 40 C.F.R. Part 156 for environmental hazards.
- 30. 40 C.F.R. § 156.10(a)(1)(viii) states that a label must clearly and prominently show the directions for used as prescribed in 40 C.F.R. § 156.10(i).
- 31. 40 C.F.R.§ 156.10(a)(4)(i) requires that the placement of the label be securely attached to such outside wrapper or container if the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read.
 - 32. 40 C.F.R. § 156.10(a)(2) states that a label shall be prominent and legible.
- 33. 40 C.F.R. § 156.500(b)(1) requires that devices that are not required to be registered under Section 3 of FIFRA, 7 U.S.C. § 136a, are subject to the requirements set forth at FIFRA Section (2)(q)(1), 7 U.S.C. §136(2)(q)(1) and Part 156 of this chapter with respect to labeling.

- 34. Based on the pictures taken during the inspections and additional pictures provided by Respondent, the label is not prominently displayed on the DJIT 300, but is inside of the machine.
- 35. Based on the pictures taken during the inspections referenced in Paragraphs 23 and 24, and additional pictures provided by Respondent, the label for DJIT 300 does not contain directions for use.
- 36. Based on the pictures taken during the inspections referenced in Paragraphs 23 and 24, and additional pictures provided by Respondent, the label for DJIT 300 does not clearly and prominently display hazard and precautionary statements.
- 37. Based on information gathered during the inspection, Respondent distributed or sold at least 2 devices between 2018 and 2020.
- 38. Respondent violated Section 12(a)(1)(F) of FIFRA, 7 U.S.C. § 136j(a)(1)(F), by distributing or selling a device which is misbranded.

Count 2 - Misbranding (*Danolyte*)

- 39. The facts stated in Paragraphs 1 through 22 above are herein incorporated.
- 40. 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 that is adulterated or misbranded.
- 41. 40 C.F.R. §156.10(a)(5)(ix) states, in pertinent part, that a pesticide or a device is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include non-numerical and/or comparative statements on the safety of the product including, but not limited to: (A) "contains all natural ingredients; (B) "among the least toxic chemicals known"; (C) "Pollution approved."
- 42. 40 C.F.R. §156.10(a)(5)(v) states, in pertinent part, that a pesticide or a device is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government.
- 43. Based on information gathered during the inspections referenced in Paragraphs 23 and 24, and provided by Respondent, the advertising and informational handout, which was provided by Respondent during sale or distribution of the *Danolyte*, states that the product is "non-toxic, safe, safe for humans and animals."
- 44. Based on information gathered during the inspections referenced in Paragraphs 23 and 24, and provided by Respondent, the handout, which accompanied the *Danolyte*,

provided by the Respondent states that the product is "approved by EPA", "EPA approved," and uses the EPA logo.

- 45. Based on information gathered during the inspection, Respondent distributed or sold *Danolyte* from 2018-2020.
- 46. Respondent violated Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), by distributing or selling a pesticide which is misbranded.

CONSENT AGREEMENT

- 47. For the purpose of this proceeding, as required by 40 C.F.R. § 22.18(b)(2), Respondent:
 - (a) admits the jurisdictional allegations set forth herein;
 - (b) neither admits nor denies the specific factual allegations stated herein;
 - (c) consents to the assessment of a civil penalty, as stated herein;
 - (d) consents to the issuance of any specified compliance or corrective action order;
 - (e) consents to any conditions specified herein;
 - (f) consents to any stated Permit Action;
 - (g) waives any right to contest the allegations set forth herein; and
 - (h) waives its rights to appeal the Final Order accompanying this Consent Agreement.
- 48. Respondent consents to the issuance of this Consent Agreement and Final Order and consents for the purposes of settlement to the payment of the civil penalty specified herein.
- 49. Respondent and EPA agree to conciliate this matter without the necessity of a formal hearing and to bear their respective costs and attorneys' fees.
- 50. Respondent consents to receiving the filed Consent Agreement and Final Order electronically at the following e-mail address(es): *jodyj@danolyteglobal.com*.

Penalty Payment

51. Respondent agrees that, in settlement of the claims alleged herein, Respondent shall pay a civil penalty of Three Thousand Dollars and No Cents (\$3,000.00) as set forth below.

52. Respondent shall pay the penalty within thirty (30) days of the effective date of the Final Order. Such payment shall identify Respondent by name and docket number and shall be by certified or cashier's check made payable to the "United States Treasury" and sent to:

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

or by alternate payment method described at http://www.epa.gov/financial/makepayment.

53. A copy of the check or other information confirming payment shall simultaneously be e-mailed to the following:

Regional Hearing Clerk R7 Hearing Clerk Filings@epa.gov and

Sara Hertz Wu, Attorney hertzwu.sara@epa.gov

54. Respondent understands that its failure to timely pay any portion of the civil penalty 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 begin to accrue on a civil or stipulated penalty from the date of delinquency until such civil or stipulated penalty and any accrued interest are paid in full. 31 C.F.R. § 901.9(b)(1). Interest will be assessed at a rate of the United States Treasury Tax and loan rates in accordance with 31 U.S.C. § 3717. Additionally, a charge will be assessed to cover the costs of debt collection including processing and handling costs, and a non-payment penalty charge of six (6) percent per year compounded annually will be assessed on any portion of the debt which remains delinquent more than ninety (90) days after payment is due. 31 U.S.C. § 3717(e)(2).

Effect of Settlement and Reservation of Rights

- 55. Full payment of the penalty proposed in this Consent Agreement shall only resolve Respondent's liability for federal civil penalties for the violations alleged herein. Complainant reserves the right to take any enforcement action with respect to any other violations of FIFRA or any other applicable law.
- 56. The effect of settlement described in the immediately preceding paragraph is conditioned upon the accuracy of Respondent's representations to EPA, as memorialized in the paragraph directly below.
- 57. Respondent certifies by the signing of this Consent Agreement that it is presently in compliance with all requirements of FIFRA and its implementing regulations.

- 58. Full payment of the penalty proposed in this Consent Agreement shall not in any case affect the right of the Agency or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. This Consent Agreement and Final Order does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of FIFRA and regulations promulgated thereunder.
- 59. Complainant reserves the right enforce the terms and conditions of this Consent Agreement and Final Order.

General Provisions

- 60. By signing this Consent Agreement, the undersigned representative of Respondent certifies that he or she is fully authorized to execute and enter into the terms and conditions of this Consent Agreement and has the legal capacity to bind the party he or she represents to this Consent Agreement.
- 61. This Consent Agreement shall not dispose of the proceeding without a final order from the Regional Judicial Officer or Regional Administrator ratifying the terms of this Consent Agreement. This Consent Agreement and Final Order shall be effective upon the filing of the Final Order by the Regional Hearing Clerk for EPA, Region 7. Unless otherwise stated, all time periods stated herein shall be calculated in calendar days from such date.
- 62. The penalty specified herein shall represent civil penalties assessed by EPA and shall not be deductible for purposes of Federal, State and local taxes.
- 63. This Consent Agreement and Final Order shall apply to and be binding upon Respondent and Respondent's agents, successors and/or assigns. Respondent shall ensure that all contractors, employees, consultants, firms, or other persons or entities acting for Respondent with respect to matters included herein comply with the terms of this Consent Agreement and Final Order.

RESPONDENT

Danolyte Global, Inc.

Date: 1-18-21

By:

Print Name

Title

IN THE MATTER OF DANOLYTE GLOBAL, INC. Docket No. FIFRA-07-2020-0185

U.S. Environmental Protection Agency	
Date:	
	Candace Bednar
	Chemical Branch Chief
	Enforcement and Compliance Assurance Division
	Sara Hertz Wu
	Office of Regional Counsel

COMPLAINANT

FINAL ORDER

Pursuant to Section 14(a) of FIFRA, 7 U.S.C. § 136*l*(a), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits, 40 C.F.R. Part 22, the foregoing Consent Agreement resolving this matter is hereby ratified and incorporated by reference into this Final Order.

Respondent is ORDERED to comply with all of the terms of the Consent Agreement. In accordance with 40 C.F.R. § 22.31(b), the effective date of the foregoing Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

IT IS SO ORDERED.		
Karina Borromeo	Date	
Regional Judicial Officer		

CERTIFICATE OF SERVICE

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

Copy via Email to Complainant:	
hertzwu.sara@epa.gov	
Copy via Email to Respondent:	
jodyj@danolyteglobal.com	
Dated this day of	
	Signed