

## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC - 4 2015

### CERTIFIED MAIL RECEIPT RETURN REQUESTED

OFFICE OF ENFORCEMENT AND COMPLIANCE ASSURANCE

David Nicholas, President Earth Sciences Laboratories, Inc. 113 SE 22<sup>nd</sup> Street, Suite 1 Bentonville, AR 72712

Re:

FIFRA Section 13 ORDER Earth Science Laboratories, Inc.

Dear Mr. Nicholas:

Enclosed is a Stop Sale, Use, or Removal Order ("Order") issued by the Environmental Protection Agency, Waste and Chemical Enforcement Division, concerning the pesticide products EarthTec (EPA Reg. No. 64962-1), PristineBlue (EPA Reg. No. 64962-1), and Cleanwater Blue (EPA Reg. No. 64962-1-82043). This Order requires Earth Science Laboratories, Inc., to immediately cease the sale, use and removal of those products in accordance with the provisions of the Order. *The Order is effective immediately upon receipt*.

Section 13(a) of FIFRA, 7 U.S.C. § 136k(a), authorizes the EPA Administrator to issue an order prohibiting the sale, use, or removal of any pesticide by any person who owns, controls, or has custody of such pesticide whenever there is reason to believe on the basis of inspection or tests that the pesticide is in violation of any provision of FIFRA or has been or is intended to be distributed or sold in violation of FIFRA. EPA has reason to believe, based on an inspection, that EarthTec, PristineBlue, and Cleanwater Blue are misbranded or unregistered pesticides and that Earth Science Laboratories, Inc. has distributed or sold, or intends to distribute or sell, those misbranded or unregistered pesticides in violation of FIFRA.

If you have any questions about this matter or wish to request an informal conference to discuss these alleged violations, you may contact Brenda Mosley, Enforcement Case Officer, at (202) 564-4166 or Tom Charlton, Attorney, at (202) 564-6960.

Sincerely,

Gregory Sullivan, Acting Director

Waste and Chemical Enforcement Division

Enclosure



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY HEADQUARTERS

In the Matter of:	) ORDER	
	SECTION 13(a)	
Earth Science Laboratories, Inc.	)	
113 SE 22nd Street, Suite 1	) FEDERAL INSECTICIDE, FUNGICIDE	
Bentonville, AR 72712	AND RODENTICIDE ACT	
	Docket No. FIFRA-HQ-2016-5005	
Respondent	) )	

## I. AUTHORITY

- 1. This Stop Sale, Use, or Removal Order ("Order") is issued pursuant to the authority vested in the Administrator of the United States Environmental Protection Agency ("EPA") by section 13(a) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended ("FIFRA"), 7 U.S.C. § 136k(a), which authorizes the Administrator of the EPA to issue an order prohibiting the sale, use or removal of any pesticide or device by any person who owns, controls or has custody of such pesticide or device whenever there is reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA.
- 2. This authority has been delegated from the EPA Administrator to the Director of the Waste and Chemical Enforcement Division, Office of Civil Enforcement, Office of Enforcement and Compliance Assurance, U.S. EPA.
- 3. Section 2(s) of FIFRA, 7 U.S.C. § 136(s), defines a "person" as "any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not."
- 4. Section 2(gg) of FIFRA, 7 U.S.C § 136(gg), defines "to 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."
- 5. Section 2(u) of FIFRA, 7 U.S.C. § 136(u), defines a "pesticide," in part, as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest." See also 40 C.F.R. § 152.15.
- 6. Section 2(p)(1) of FIFRA, 7 U.S.C. § 136(p)(1), defines "label" as the "written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or

wrappers."

- 7. Section 2(p)(2) of FIFRA, 7 U.S.C. § 136(p)(2), defines "labeling" as "all labels and all other written, printed, or graphic matter—
  - (A) accompanying the pesticide or device at any time; or
  - (B) to which reference is made on the label or in literature accompanying the pesticide...."
- 8. Section 2(q)(1) of FIFRA, 7 U.S.C. § 136(q)(1), states that a "pesticide is misbranded if—
  - (A) Its labeling bears any statement, design or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;
  - (E) 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 (as compared to other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions or purchase and use;
  - (F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environment;
  - (G) the label does not contain a warning or caution statement which may be necessary and if complied with together with any requirements imposed under section 3(d) of the Act, are adequate to protect health and the environment[.]"
- 9. The EPA's regulations at 40 C.F.R. § 156.10(a)(5) provides examples of false or misleading statements that can cause a pesticide to be misbranded. They include but are not limited to:
  - (a) A false or misleading statement concerning the composition of the product (40 C.F.R. § 156.10(a)(5)(i));
  - (b) A false or misleading statement concerning the effectiveness of the pesticide or device (40 C.F.R. § 156.10(a)(5)(ii));
  - (c) A false or misleading statement about the value of the product for purposes other than as a pesticide or device (40 C.F.R. § 156.10(a)(5)(iii));
  - (d) A false or misleading comparison with other pesticides or devices (40 C.F.R. §

156.10(a)(5)(iv));

- (e) Any statement directly or indirectly implying that the pesticide is recommended and endorsed by any agency of the Federal Government (40 C.F.R. § 156.10(a)(5)(v));
- (f) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling (40 C.F.R. § 156.10(a)(5)(vi));
- (g) A true statement used in such a way as to give a false or misleading impression to the purchaser (40 C.F.R. § 156.10(a)(5)(vii));
- (h) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations (40 C.F.R. § 156.10(a)(5)(viii));
- (i) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous, "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed" (40 C.F.R. § 156.10(a)(5)(ix)).
- 10. 40 C.F.R. § 156.10(a)(vii) requires that every pesticide product bear a label that has "[h]azard and precautionary statements as prescribed in Subpart D of this part, for human and domestic animals hazards, and Subpart E of this part for environmental hazards."
- 11. Section 3(a) of FIFRA, 7 U.S.C. § 136a, provides that "no person in any State may distribute or sell to any person any pesticide that is not registered under this Act."
- 12. 40 C.F.R. § 152.15 provides that "no person may distribute or sell any pesticide that is not registered under the Act," with certain exceptions not applicable here.
- 13. 40 C.F.R. § 152.132 provides that for a supplemental distributor pesticide product "[t]he distributor is considered an agent of the registrant for all intents and purposes under the Act, and both the registrant and the distributor may be held liable for violations pertaining to the distributor product."
- 14. 40 C.F.R. § 152.132(a) requires for each supplemental distributor pesticide product that the registrant submit a notification containing distributor and product information to the EPA.
- 15. Section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A), declares it unlawful for any person in any State to distribute or sell to any person an unregistered pesticide.
- 16. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), provides that it is unlawful for any person in any State to distribute or sell to any person any pesticide which is adulterated or misbranded.

- 17. Section 12(a)(2)(S) of FIFRA, 7 U.S.C. § 136(a)(2)(G), provides that it shall be unlawful to violate any regulation issued under FIFRA section 3(a) or section 19.
- 18. Section 12(a)(2)(I) of FIFRA, 7 U.S.C. § 136j(a)(2)(I), provides that it shall be unlawful for any person to violate any order issued under section 13 of FIFRA.

## II. BACKGROUND

- 19. This Order refers to Earth Science Laboratories, Inc. and all its divisions, offices and branches, collectively, as "Earth Science Laboratories," the "Registrant," or the "Respondent."
- 20. Earth Science Laboratories is a corporation located and incorporated in the state of Arkansas. Earth Science Laboratories is a "person" as defined in section 2(s) of FIFRA, 7 U.S.C. § 136(s).
- 21. Earth Science Laboratories is the registrant of EarthTec, a pesticide which has been assigned the EPA Registration Number (EPA Reg. No.) 64962-1. The active ingredient in EarthTec is copper sulfate pentahydrate (CAS No. 7758-99-8).
- 22. EarthTec is a pesticide as defined under section 2(u) of FIFRA, 7 U.S.C. § 136(u).
- 23. On July 22, 1991, the EPA conditionally approved the registration for the product EarthTec as an algicide and bactericide for lakes, ponds, reservoirs, canals, lagoons, pools, spas, hot tubs, and other water systems.
- 24. As part of the initial registration approval, the EPA approved the use of an alternative brand name, "PristineBlue."
- 25. It is a common practice for a registered product to have alternate brand names. In accordance with 40 CFR § 152.46 and Pesticide Registration (PR) Notice 98-10, alternate brand names are submitted to the EPA for approval using the notification procedures outlined in that PR Notice.
- 26. Over the years, the EPA has approved the use of a number of other alternate brand names for EarthTec. They include: EarthTec QZ, Algae Shield, AgriTec, AgriTec 2, CopChek, Aqua Solution, High Country Footbath, Faze 1, Aquadrop, Pond Boss, Rice-Cop 5, Cleanwater Blue, Radiance, and Rezonate.
- 27. Of the above-listed alternative brand names, Cleanwater Blue (EPA Reg. No. 64962-1-82043), Radiance (EPA Reg. No. 64962-1-83940), Aquadrop (EPA Reg. No. 64962-1-85829), and Pond Boss (EPA Reg. No. 64962-1-84732) are known to be, or known to have been, supplemental distributor products.

- 28. For the purposes of this SSURO, EarthTec and its various brand names under the master label and sub-labels that are distributed or sold by Earth Science Laboratories, including the supplemental distributor products, are collectively referred to as "EarthTec pesticide products."
- 29. All EarthTec pesticide products are currently produced at an Earth Science Laboratories facility located at 515 Brown Street, Holdrege, Nebraska 68949. That facility is registered with EPA as a pesticide producing establishment and assigned the EPA Establishment Number 64962-NE-001.
- 30. The current registration for EarthTec provides for use as an algaecide, a bactericide for non-public health bacteria, and a molluscicide in a variety of locations, including but not limited to: impounded waters, lakes, and ponds; potable water supplies; irrigation systems, canals, and ditches; pools, spas, and hot tubs; and feed lot run-off lagoons and organic sludge pits.
- 31. The EPA-approved labeling for EarthTec contains an Environmental Hazard Statement in accordance with 40 C.F.R. § 156.10(a)(vii) and Subpart E.
- 32. Earth Science Laboratories uses a variety of websites to communicate information about its products, including "pristineblue.com," "www.earthtecqz.com," "algaeshield.com," "www.earthsciencelabs.com," "www.earthtecwatertreatment.com," and "cleanwaterfortheplanet.com" (which directs readers to the EarthTec product website). References to the product-specific websites are found on the FIFRA product labels for the following EarthTec pesticide products: EarthTec, Pristine Blue, Cleanwater Blue, and Radiance.

## III. BASIS FOR THE ORDER

- 33. Beginning in April 2015, the Office of Civil Enforcement received information from the Office of Pesticide Programs regarding potential FIFRA violations associated with Earth Science Laboratories' EarthTec pesticide products line.
- 34. On October 14, 2015, federally-credentialed inspectors performed an inspection of the Earth Science Laboratories production establishment in Holdredge, Nebraska.
- 35. During the October 14, 2015, inspection, the inspectors obtained product samples and related documentation for PristineBlue, EarthTec, Cleanwater Blue, and other pesticide products produced by and/or registered to Earth Sciences Laboratories. Review of the sampled products and the accompanying documentation revealed the following observations, as referenced in Paragraphs 36 through 69, below.

#### A. PristineBlue

- 36. The product label for PristineBlue lacks the Environmental Hazard Statement as contained on the EPA-registered EarthTec Master Label. Failure to include this Environmental Hazard Statement on the PristineBlue label causes the product to be misbranded pursuant to FIFRA sections 2(q)(1)(E) and (G), 7 U.S.C. §§ 136(q)(1)(E) and (G), because its label: (1) is missing information that is required to be placed on the label and (2) does not contain a warning or hazard statement that is adequate to protect health and the environment.
- 37. For the PristineBlue product line, Earth Science Laboratories developed and distributes the document "PristineBlue Pool & Spa Care Guide," © 2015 ("Pool & Spa Care Guide"), a 24-page, full color brochure that provides detailed information on the PristineBlue product line and product use, including dosing instructions and maintenance application instructions.
- 38. The EPA has reason to believe that the Pool & Spa Care Guide is distributed to PristineBlue Customers by the Registrant and PristineBlue retailers.
- 39. The Pool & Spa Care Guide is labeling pursuant to FIFRA section 2(p)(2)(A), 7 U.S.C. § 136(p)(2)(A), because it accompanies the PristineBlue pesticide product.
- 40. The Pool and Spa Care Guide was also found on, and was available to download from, the PristineBlue Website: http://pristineblue.com/PoolSpaGuide2015.pdf (October 14, 2015).<sup>2</sup> The website, including its address, is referenced on the PristineBlue product labels.
- 41. The Pool & Spa Guide is labeling pursuant to FIFRA section 2(p)(2)(B), 7 U.S.C. § 136(p)(2)(B), because it was on the website referenced on the Pristine Blue product labels.
- 42. On Page 1 of the Pool & Spa Care Guide, Earth Science Laboratories states that swimming in a pool treated with PristineBlue algaecide/bactericide is "like swimming in bottled water!" EPA considers this statement to be false and misleading regarding the product's safety. PristineBlue/EarthTec is a Toxicity Category Class II Pesticide, the second-most toxic pesticide classification under EPA's labeling regulations at 40 C.F.R. § 156.62, and as indicated on the EarthTec master label (dated July 24, 2015), PristineBlue can cause substantial eye injury and is harmful if swallowed or absorbed through the skin. PristineBlue is also toxic to fish and aquatic invertebrates. Therefore, the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
- 43. In the Pool & Spa Care Guide, Earth Science Laboratories states in the Contents Section (no page number) that PristineBlue is a "non-chlorine alternative system[.]" On Page 12, the Pool & Spa Care Guide also states that PristineBlue customers "can relax with the knowledge that the water is being treated without the irritating effects of chlorine or

System, http://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1 (last visited December 2, 2015).

<sup>&</sup>lt;sup>1</sup> Enclosed with a Label Amendment to EarthTec, dated October 20, 2015 (titled: Label Amendment – Deletes "Store EarthTec in its original container only"). Accessible on the EPA internet site titled Pesticide Product Labeling

<sup>&</sup>lt;sup>2</sup> Last downloaded from PristineBlue's website on October 14, 2015. It was no longer available to download on November 4, 2015.

bromine." Chlorine systems are well-known to be primary disinfectants when used in pools and spas. PristineBlue is not registered for use as a primary disinfectant. Therefore, the claim that PristineBlue is a non-chlorine alternative is false and misleading and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), and C.F.R. § 156.10(a)(5)(ii).

44. On Page 11 of the Pool & Spa Care Guide there are directions to apply PristineBlue at maintenance dosage rates to swimming pools that are substantially higher than what is authorized under EarthTec's FIFRA Master Label (Page 11) as detailed in the table below:

Care Guide and E the Amount o	arthTec Master FIFI of Product Needed to	e Rates Between Pristin RA Label (dated Octobe be Added to 10,000 Gal Parts Per Million (PPM	er 20, 2015) Showing lons to Reach a
Measured Metallic Copper Level As Expressed in Parts per Million	EarthTec Master FIFRA Label (fl oz)	PristineBlue Pool and Spa Care Guide (fl oz)	Exceedance of previously accepted application rate
0.90 ppm	0	0	NA
0.80 ppm	2	4	100%
0.70 ppm	4	6	50%
0.60 ppm	6	8	33.3%
0.50 ppm	8	11	37.5%
0.40 ppm	.11	13	18.1%
0.30 ppm	13	15	15.3%
0.20 ppm	15	17	13.3%
0.10 ppm	17	20	17.6%

- 45. The Pool & Spa Care Guide dosage directions described in Paragraph 44 above are false and misleading statements because they do not accurately portray the dosage rates that the EPA authorized under EarthTec's FIFRA registration. As such, this product's labeling does not contain directions for use which are necessary for effecting the purpose for which the product was intended and if complied with are adequate to protect health and the environment. Therefore, the product is considered to be misbranded pursuant to sections 2(q)(1)(A) and (F) of FIFRA, 7 U.S.C. §§ 136(q)(1)(A) and (F).
- 46. On Page 15 of the Pool & Spa Care Guide there are directions to apply PristineBlue at maintenance dosage rates to spas that are substantially higher than what is authorized under EarthTec's FIFRA Master Label (Page 12) as detailed in the table below. (While this table addresses 500 gallons, there are numerous exceedances at other spa water volumes (e.g., 100, 200, 300, 600, 700, 800, and 1,000 gallons).)

Table Comparing Maintenance Dosage Rates Between PristineBlue Pool and Spa
Care Guide and EarthTec Master FIFRA Label (dated October 20, 2015) Showing
the Amount of Product Needed to be Added to 500 Gallons to Reach a
Concentration of 0.9 Parts Par Million (PPM)

Measured Metallic Copper Level As Expressed in Parts	EarthTec Master FIFRA Label (Milliliters)	PristineBlue Pool and Spa Care Guide (Milliliters)	Exceedance of previously accepted application rate
per Million 0.90 ppm	0	0	NA
0.80 ppm	3	6	100%
0.70 ppm	6	9	50%
0.60 ppm	9	13	44.4%
0.50 ppm	13	16	23.1%
0.40 ppm	16	19	18.7%
0.30 ppm	19	23	21%
0.20 ppm	22	26	18.1%
0.10 ppm	25	29	16%

- 47. The Pool & Spa Care Guide dosage directions described in Paragraph 46 above are false and misleading statements because they do not accurately portray the dosage rates that the EPA authorized under EarthTec's FIFRA registration. As such, this product labeling does not contain directions for use which are necessary for effecting the purpose for which the product was intended and if complied with are adequate to protect health and the environment. Therefore, the product is considered to be misbranded pursuant to sections 2(q)(1)(A) and (F) of FIFRA, 7 U.S.C. §§ 136(q)(1)(A) and (F).
- 48. Earth Science Laboratories developed and distributes the "PristineBlue Pool/Spa Maintenance Dosage Calculator" (the "Dosage Calculator"), © 2015, an approximately 3.75-by-7.5 inch laminated cardstock sliding calculator that provides detailed information on product use, instructions, and dosage levels for maintaining PristineBlue and other chemicals in pools and spas; a toll-free number for technical support; and contact information for the PristineBlue website.
- 49. The EPA has reason to believe that the Dosage Calculator is provided to PristineBlue retailers who in turn provide it to PristineBlue customers.
- 50. The Dosage Calculator is labeling pursuant to section 2(p)(2)(A) of FIFRA, 7 U.S.C. § 136(p)(2)(A), because it accompanies the PristineBlue pesticide product.
- 51. The Dosage Calculator contains directions for use that apply PristineBlue at rates higher than what is found in the approved master label (as described in Paragraphs 44 and 46 above). For pools of 10,000 gallons and spas of 500 gallons, the Dosage Calculator

- exceedances are identical to what was found in the Pool and Spa Care Guide as described above in Paragraphs 44 and 46.
- 52. The maintenance dosage rates in the Dosage Calculator are false and misleading statements because they do not accurately portray the dosage rates that the EPA authorized under FIFRA registration. As such, this product labeling does not contain directions for use which are necessary for effecting the purpose for which the product was intended and if complied with are adequate to protect health and the environment. Therefore, the product is considered to be misbranded pursuant to sections 2(q)(1)(A) and (F) of FIFRA, 7 U.S.C. §§ 136(q)(1)(A) and (F).
- 53. PristineBlue's Product Website, http://pristineblue.com (last visited Nov. 4, 2015), informs customers and potential customers about PristineBlue and to provide application assistance to product users. The website is labeling because it is referenced on the product label for PristineBlue products.
- 54. On the testimonial section of PristineBlue's website, http://pristineblue.com/Testimonials.asp (last visited Nov. 4, 2015), the Registrant publishes numerous unapproved statements implying that PristineBlue is safe or harmless to humans, including: "the safest and most cost-effective sanitizer the industry has to offer," "PristineBlue is safe for children," "it does not burn the eyes of your children," "no burning eyes," "non-corrosive," "environmentally friendly," "ecofriendly," "does not burn your eyes or the eyes of your children," "softer on their hair and skin," and "you can add Pristineblue as an additive to your drinking water."
- 55. These statements are false and misleading because they imply that PristineBlue is harmless. As noted in Paragraph 42 above, PristineBlue is a Toxicity Category Class II Pesticide that can cause substantial eye injury and is harmful to humans if swallowed or absorbed through the skin. It is also toxic to fish and aquatic invertebrates. Therefore, the product labeling as contained on the Pristine Blue website, contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
- 56. Throughout the PristineBlue website there are unqualified statements that PristineBlue controls "bacteria." Http://pristineblue.com/pools.asp (last visited Nov. 4, 2015), http://pristineblue.com/faq.asp (last visited Nov. 4, 2015). However, EarthTec is only registered to control non-public health bacteria; it is not registered to control public health bacteria. Public health bacteria claims are subject to greater level of the EPA review during registration. See 40 C.F.R. §§ 158.30(c), 158.2070, 158.2160, and 158.2220. EarthTec has not been subjected to that level of review. Failure to distinguish between the two on product labeling is a false and misleading statement regarding the effectiveness of the product. Therefore, the product labeling as contained on the PristineBlue website, contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A), and C.F.R. § 156.10(a)(5)(ii).

#### B. EarthTec

- 57. The EarthTec website address, http://www.cleanwaterfortheplanet.com (last visited Nov. 4, 2015), is referenced on the EarthTec product labels. That website automatically redirects anyone who links to it to another website, www.earthtecwatertreatment.com (last visited Nov. 4, 2015). Because of the website reference on the EarthTec product labels, these linked websites are considered labeling as defined under FIFRA § 2(p)(2)(B), 7 U.S.C. § 136(p)(2)(B).
- 58. The website labeling contains numerous statements that EarthTec controls "bacteria" which can be read broadly to imply that EarthTec controls all types of bacteria, including both pathogenic and non-pathogenic. These statements can be found on the following sections of the EarthTec webpage (www.earthtecwatertreatment.com (last visited Nov. 4, 2015)): "about," "agricultural," "applications," "fresh food," "industrial," "irrigation," "products," and "technology." EPA considers these statements to be false and misleading with respect to the product's effectiveness pursuant to 40 C.F.R. § 156.10(a)(5)(ii) because EarthTec is only registered to control non-public health bacteria; it is not registered to control public health bacteria. Therefore, this product labeling contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
- 59. The website labeling contains numerous claims that EarthTec can be used as a fungicide. EPA considers this statement to be false and misleading because while EarthTec's master label provides for the use of this pesticide as an algaecide, a bactericide, and a molluscicide, it does not authorize this pesticide product's use as a fungicide. Therefore, this product labeling contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
- 60. The EarthTec website's "Fresh Food" page (http://www.earthtecwatertreatement.com/freshfood.aspx (last visited Nov. 4, 2015)), contains the following statements:
  - (a) EarthTec "is used commercially to control the bacteria and fungi that cause spoilage in harvested fruits and vegetables[,]" and
  - (b) "EarthTec can reduce spoilage bacteria and fungi on fruit, vegetables, chicken, and fish[.]"
- 61. EPA considers these statements to be false and misleading because the EarthTec master label does not authorize the use of EarthTec on fruits or vegetables or to be used to control fungi. Therefore, this product labeling contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).
- 62. The EarthTec website's "Products" page (http://www.earthtecwatertreatement.com/products.aspx (last visited Nov. 4, 2015)),

contains a bulleted list of product performance capabilities of EarthTec. One of those efficacy claims is "E.Coli Reduction." EPA considers this statement to be false and misleading because EarthTec is not registered to control public health bacteria such as E.Coli and has not submitted to the EPA any data to show EarthTec's efficacy in controlling E.Coli. Therefore, this product labeling contains false and misleading statements and the product is considered to be misbranded pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A).

#### C. Cleanwater Blue

- 63. Cleanwater Blue is identified on its label as a supplemental distributor pesticide product under the EarthTec product registration through referencing its registration number as EPA Registration Number 64962-1-82043.
- 64. Cleanwater Blue is produced by Earth Sciences Laboratories at its Holdrege, Nebraska, pesticide producing establishment.
- 65. The EPA has reason to believe that the product, Cleanwater Blue, is shipped by Earth Science Laboratories to the distributor, The Spa Depot, Inc., at 8910 Select Ct., SE, Olympia, WA, 98501.
- 66. The EPA has no record that Earth Science Laboratories submitted a notification to the EPA regarding Cleanwater Blue's status as a supplemental distributor pesticide product as required by 40 C.F.R.§ 152.132(a).
- 67. Without this notification, Cleanwater Blue is considered an unregistered pesticide product whose distribution and sale is prohibited under section 12(a)(1)(A) of FIFRA, 7 U.S.C. § 136j(a)(1)(A).
- 68. Without this notification, Cleanwater Blue is considered a misbranded pesticide pursuant to section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q)(1)(A) because its label portraying Cleanwater Blue as a supplemental distributor product is false and misleading.
- 69. The product label for Cleanwater Blue is missing an Environmental Hazard Statement required pursuant to 40 C.F.R. § 156.80. Failure to have the required Environmental Hazard Statement makes Cleanwater Blue a misbranded pesticide product pursuant to sections 2(q)(1)(E) and (G) of FIFRA, 7 U.S.C. §§ 136(q)(1)(E) and (G), because its label is (1) missing information that is required to be placed on the label and (2) does not contain a warning or hazard statement which may be necessary and if complied with is adequate to protect health and the environment.

#### D. Summary of Basis for the Order

70. In light of the allegations made above in Paragraphs 36 to 69, the EPA has reason to believe that these EarthTec pesticide products are misbranded and/or unregistered pesticides that are

being distributed or sold or intended to be distributed or sold in violation of sections 12(a)(1)(A) and 12(a)(1)(E) of FIFRA, 7 U.S.C. §§ 136j(a)(1)(A) and 136j(a)(1)(E).

#### ORDER

- 71. Pursuant to the authority of section 13(a) of FIFRA, 7 U.S.C. § 136k(a), the EPA hereby orders Earth Science Laboratories to **immediately cease** the sale, use, or removal of the following pesticide products under its ownership, control, or custody, wherever such EarthTec pesticide products are located, except in accordance with the provisions of this Order.
  - (a) PristineBlue (EPA Reg. No. 64962-1),
  - (b) EarthTec (EPA Reg. No. 64962-1), and
  - (c) Cleanwater Blue (EPA Reg. No. 64962-1-82043).<sup>3</sup>
- 72. This Order shall apply to all quantities and container types and sizes of the products identified above controlled or within the custody of Earth Science Laboratories intended for sale or distribution, including PristineBlue, EarthTec, and Cleanwater Blue stocks returned to Earth Science Laboratories from its customers or other endusers.
- 73. The EarthTec products identified above in Paragraph 71 shall not be used, sold, offered for sale, held for sale, shipped, delivered for shipment, received, or having so received, shall not be delivered, offered for delivery, moved, or removed for disposal from any facility or establishment, for any reason, unless approved by the EPA in writing. Any proposal for movement of the EarthTec pesticide products shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:
  - (a) the purpose for which the movement is being requested;
  - (b) an accounting of the quantities of product to be moved, including location(s), quantities from each location and container size for the products to be moved; and
  - (c) the destination location to which the product will be moved.
- 74. Within 48 hours of receipt of this Order, Earth Science Laboratories will:
  - (a) remove any false and misleading statements from any website under its control for the EarthTec pesticide products identified above in Paragraph 71 and

<sup>&</sup>lt;sup>3</sup> Since the EPA has no evidence showing this product was properly registered as a supplemental distributor pesticide product, the referenced number is used solely for product identification purposes and its use in this Order does not reflect an EPA belief that this product is properly registered.

- (b) cease distributing or making available the Pristine Blue Pool & Spa Care Guide and the PristineBlue Pool/Spa Maintenance Dosage Calculator identified in Paragraphs 37 and 48, above.
- 75. Within 10 days of receipt of this Order, Earth Science Laboratories shall submit to the EPA an accounting of all EarthTec pesticide products subject to this Order. The report shall be submitted to James Miles, Chief, Pesticides and Tanks Enforcement Branch (2249A), United States Environmental Protection Agency, 1200 Pennsylvania Ave., N.W., Washington, DC 20460, and shall include:
  - (a) A description of all existing EarthTec pesticide product inventory, including the location(s) where the products are held, quantities, and container sizes. Earth Science Laboratories must update the information on a weekly basis for four weeks, on a monthly basis for the following six months, and thereafter only upon further changes to the information;
  - (b) A complete list of Earth Science Laboratories' distributors and direct-sale customers and records of all sales and distributions made to such entities for the listed EarthTec pesticide products since January 1, 2014; and
  - (c) Provisions to maintain records of the disposition (e.g., reformulation, repackaging, relabeling, disposal) of the EarthTec pesticide products and to make the records available to the EPA upon request. Such records must include information on the method, the quantity, and the location of disposition and/or disposal.
- 76. Any agent, owner, or operator of Earth Science Laboratories violating the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in section 14 of FIFRA, 7 U.S.C. § 136l.
- 77. The issuance of this Order shall not constitute a waiver by the EPA of its remedies, either judicial or administrative, under FIFRA or any other federal environmental law to address this matter or any other matters or unlawful acts not specified in this Order.
- 78. This Order shall be effective immediately upon receipt by Earth Science Laboratories or any agents of Earth Science Laboratories.
- 79. This Order shall remain in effect unless and until revoked, terminated, suspended or modified in writing by the EPA.
- 80. If any provision or provisions of this Order is/are subsequently held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby and they shall remain in full force and effect.

## V. OTHER MATTERS

Respondent may seek federal judicial review of this Order pursuant to section 16 of FIFRA, 7 U.S.C. § 136n.

For any additional information about this Order, please contact Brenda Mosley, Enforcement Case Officer, at 202-564-6960 or Tom Charlton, Attorney, at 202-564-6960.

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Gregory Sullivan, Acting Director

Waste and Chemical Enforcement Division

Docket No. FIFRA-HQ-2016-5005 FIFRA § 13(a) ORDER