

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,
Plaintiff,

v.

INHANCE TECHNOLOGIES LLC,

Defendant.

Civ. No. _____

COMPLAINT

Plaintiff, the United States of America (the “United States”), by the authority of the Attorney General and through the undersigned attorneys, and at the request of the Administrator of the United States Environmental Protection Agency (the “EPA”), files this Complaint and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action brought pursuant to Section 17(a) of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2616(a), and the Declaratory Judgment Act, 28 U.S.C. § 2201, to obtain declaratory and injunctive relief against Inhance Technologies LLC (the “Defendant” or “Inhance”).

2. The Defendant has and continues to [REDACTED]

[REDACTED] in violation of TSCA and its implementing regulations.

3. [REDACTED]

[REDACTED]. Scientific studies have linked exposure to [REDACTED] with a range of adverse health impacts on humans and animals and harm to the environment.

4. The Defendant's pertinent act or omissions violate Sections 5, 15, and 17 of TSCA, 15 U.S.C. §§ 2604, 2614, and 2616, respectively, and Part 721 of the regulations implementing TSCA, specifically, 40 C.F.R. §§ 721.25 and 721.35.

5. The Defendant has and continues to violate the statutory and regulatory provisions referenced in paragraph 4 by engaging in ongoing "significant new uses" [REDACTED]

[REDACTED]
[REDACTED] Significant New Use Rule [REDACTED]
Rule"), [REDACTED], without complying with the applicable statutory and regulatory process for engaging in such significant new uses.

6. Under Section 5(a)(1) of TSCA, 15 U.S.C. § 2604(a)(1), no person may manufacture or process a chemical substance for a significant new use unless (1) that person submits a Significant New Use Notice ("New Use Notice") to the EPA; (2) the EPA reviews that notice; and (3) the EPA makes a determination on that use under Section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3). Title 40 C.F.R. § 721.25 prescribes similar requirements for any person seeking to engage in a significant new use of a chemical substance.

7. Under Section 15 of TSCA, 15 U.S.C. § 2614, it is a prohibited act to fail or refuse to comply with any requirement of TSCA or any rule promulgated under TSCA. Under 40 C.F.R. § 721.35, it is a violation of Section 15 of TSCA to fail to comply with any provision of Title 40, Part 721 of the regulations implementing TSCA.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over the subject matter of this action pursuant to Section 17(a) of TSCA, 15 U.S.C. § 2616(a), and 28 U.S.C. §§ 1331 and 1345.

9. Venue is proper in this judicial district pursuant to Section 17(a) of TSCA, 15 U.S.C. § 2616(a), and 28 U.S.C. §§ 1391(b). An act, omission, or transaction constituting a

violation of Section 15 of TSCA, 15 U.S.C. § 2614, has occurred or the Defendant is found or transacts business in this judicial district.

PARTIES

10. The Plaintiff is the United States of America, acting at the request of the EPA, an agency of the United States.

11. The Defendant is a limited liability company formed in the State of Delaware and doing business in [REDACTED]

[REDACTED]

[REDACTED].

12. The Defendant is a “person,” as defined under 40 C.F.R. § 720.3(x), subject to the requirements of TSCA. 15 U.S.C. § 2601, *et seq.*

RELEVANT STATUTORY AND REGULATORY FRAMEWORK

13. TSCA establishes a scheme designed, among other things, to provide the EPA with the authority “to regulate chemical substances and mixtures that present an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2601(b)(2).

14. Pursuant to Section 5(a)(2) of TSCA, 15 U.S.C. § 2604(a)(2), the EPA is authorized to promulgate significant new use rules. Once the EPA determines in a significant new use rule that the manufacturing or processing of a chemical substance for a use constitutes “a significant new use” under TSCA, a manufacturer or processor must submit to EPA a New Use Notice for EPA review before manufacturing or processing the substance for that use. 15 U.S.C. § 2604(a)(1).

15. Pursuant to Section 5(a) of TSCA, 15 U.S.C. § 2604(a), no person may manufacture or process any chemical substance for a use which the EPA has determined is a significant new use under Section 5(a)(2) of TSCA, 15 U.S.C. § 2604(a)(2), unless (1) the person

submits to the EPA, at least 90 days before such manufacture or processing, a New Use Notice, as required by Section 5(a)(1)(B), 15 U.S.C. § 2604(a)(1)(B), and 40 C.F.R. § 721.25, of such person's intention to manufacture or process such substance; (2) such person complies with any applicable requirement imposed by Sections 5(b), (e), or (f) of TSCA, 15 U.S.C. §§ 2604(b), (e), or (f); (3) the EPA conducts a review of the notice; (4) the EPA makes a determination in accordance with Section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3); and (5) the EPA takes the actions required in association with that determination.

16. Under 40 C.F.R. § 721.25, each person who is required to submit a significant new use notice under Part 721 must submit the notice at least 90 calendar days before commencing manufacture or processing of a chemical substance identified for a significant new use. The submitter must comply with any applicable requirement of Section 5(b) of TSCA, 15 U.S.C. § 2604(b), and the notice must include the information and test data specified in Section 5(d)(1) of TSCA, 15 U.S.C. § 2604(d)(1).

17. Following the submission to the EPA of a New Use Notice, the EPA is required to review the New Use Notice to determine whether the relevant chemical substance or significant new use presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation. Section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3).

18. If the EPA reviews the New Use Notice and determines that (A) the information available is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which a notice is required, or (B) in the absence of sufficient information to permit the EPA to perform such an evaluation, the manufacture,

processing distribution in commerce, use, or disposal of such substance, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, or (C) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, then the EPA must issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of such substance to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, Section 5(e) of TSCA. 15 U.S.C. § 2604(e).

19. If the EPA determines that a chemical substance or significant new use with respect to which notice is required presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, the EPA must take actions to the extent necessary to protect against such risk, including issuing a rule or order to prohibit or limit the manufacture, processing, or distribution in commerce of such substance. Section 5(f) of TSCA, 15 U.S.C. § 2604(f).

20. The EPA has promulgated a number of significant new use rules. *See generally* 40 C.F.R. § 721, subpart (E). These rules specify the types of uses of particular substances that qualify as “significant new uses” of those substances. *See generally* 40 C.F.R. § 721, subpart (E). Among the significant new use rules promulgated by the EPA is the [REDACTED] Rule [REDACTED].

21. [REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

22. The [REDACTED] Rule [REDACTED]

[REDACTED]

[REDACTED]

23. The [REDACTED] Rule [REDACTED]

[REDACTED] For example, one significant new use is

[REDACTED]

[REDACTED]

24. [REDACTED] Rule, Inhance's past and continuing manufacturing

[REDACTED] subject to that rule, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Rule. [REDACTED]

[REDACTED]

25. It is unlawful for any person to: (1) fail or refuse to comply with any requirement of TSCA or any rule promulgated, order issued, or consent agreement entered into under TSCA; (2) use for commercial purposes a chemical substance which such person knew or had reason to know was manufactured or processed in violation of Section 5 of TSCA, 15 U.S.C. § 2604; or (3) fail or refuse to submit notices as required by TSCA or any rule promulgated under the statute. Section 15 of TSCA, 15 U.S.C. § 2614.

26. Under 40 C.F.R. § 721.35, the failure to comply with any provision of Part 721 (Significant New Uses of Chemical Substances) is a violation of Section 15(1) of TSCA, 15

U.S.C. § 2614(1). Using a chemical substance for commercial purposes that a person knew or had reason to know was manufactured or processed in violation of Part 721 also is a violation of Section 15(2) of TSCA, 15 U.S.C. § 2614(2).

27. Pursuant to Section 17(a)(1), 15 U.S.C. § 2616(a) of TSCA, the district courts of the United States have jurisdiction over civil actions to (A) restrain any violation of Section 15 of TSCA, 15 U.S.C. § 2614; (B) restrain any person from taking any action prohibited under Section 5 of TSCA, 15 U.S.C. § 2604; (C) compel the taking of any action required by or under TSCA; and (D) direct any manufacturer or processor of a chemical substance subject to subject to a rule or order under Section 5 of TSCA, 15 U.S.C. § 2604, and distributed in commerce to (i) give notice of such fact to distributors in commerce of such substance, and to other persons in possession of such substances or exposed to such substances; (ii) to give public notice of such risk of injury; and (iii) either replace or repurchase such substance.

28. Under the Declaratory Judgment Act, 28 U.S.C. § 2201, where an actual case or controversy exists, a court may issue a binding decree that defines the rights and obligations of the parties.

GENERAL ALLEGATIONS

29. The Defendant is a company that uses [REDACTED]
[REDACTED]

[REDACTED]

30. [REDACTED]
[REDACTED]
[REDACTED]

31. Inhance manufactures for a significant new use [REDACTED]

[REDACTED] Rule as a byproduct of its [REDACTED] processes.

32. The term “byproduct” is defined under the TSCA regulations as “a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.” 40 C.F.R. § 720.3(d).

33. Between August and October 20, 2020, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED] Rule.

34. In December 2020, [REDACTED]

35. The EPA tested the [REDACTED] referred to in paragraph 34 and detected several [REDACTED] Rule in the [REDACTED]

36. On information and belief, the [REDACTED] that the EPA tested for the presence of [REDACTED] by Inhance.

37. On January 14, 2021, the EPA issued a subpoena to Inhance pursuant to Section 11(c) of TSCA, 15 U.S.C. § 2610(c), to obtain information concerning Inhance’s [REDACTED]

38. On February 1 and 8, 2021, Inhance responded to the EPA’s subpoena.

39. Based on the information Inhance provided, the EPA determined that Inhance’s processes for [REDACTED] results in the manufacturing for a significant new use of

[REDACTED] Rule [REDACTED]
[REDACTED]

40. On March 1, 2022, the EPA issued a Notice of Violation (“NOV”) to Inhance notifying Inhance that its process [REDACTED] [REDACTED] Rule and that Inhance’s manufacturing or processing of such [REDACTED] is a violation of the [REDACTED] Rule.

41. The NOV requested any information on any changes Inhance may have made to its [REDACTED] process and any information that would confirm that any such changes eliminated the manufacture of [REDACTED] subject to the [REDACTED] Rule.

42. The NOV further stated that if Inhance had not changed its process for [REDACTED] [REDACTED] to prevent the manufacture of [REDACTED] Inhance must immediately cease the manufacture of [REDACTED] subject to the [REDACTED] Rule and may not resume manufacture until it has submitted a New Use Notice and the EPA issues a determination on that New Use Notice.

43. Between April and August 2022, the EPA reviewed additional information submitted by Inhance and also determined that Inhance’s [REDACTED] is manufacturing [REDACTED] subject to the [REDACTED] Rule.

44. In August 2022, the EPA determined that the information Inhance provided on its [REDACTED] processes is inadequate to support a determination that the process does not result in the manufacture of [REDACTED] Rule.

45. On September 7, 2022, Inhance informed the EPA that, although it intended to submit New Use Notices regarding [REDACTED] Rule manufactured in

its [REDACTED] processes, Inhance did not intend to cease its [REDACTED] processes before or during the period of review of the New Use Notices.

46. The Defendant has [REDACTED] regarding the manufacture of

[REDACTED] Rule in Defendant's process for [REDACTED] [REDACTED].

47. The information and test data [REDACTED] indicates that Inhance's process for [REDACTED] continues to result in the production for a significant new use of [REDACTED] Rule.

48. Studies involving humans and animals have shown that certain [REDACTED] [REDACTED] Rule can bioaccumulate in the body (e.g., serum half-lives from months to years in humans and monkeys; hours to days or months in rodents).

49. Certain [REDACTED] Rule [REDACTED] examined in the studies referenced in paragraph 48 have been detected in [REDACTED] by Inhance.

50. Epidemiological studies in human populations and experimental animal studies show correlations between exposures to certain [REDACTED] and an array of cancer and non-cancer health effects, including to susceptible subpopulations (e.g., those in early developmental life and women of child-bearing age).

51. Inhance's past and continuing manufacturing for a significant new use of [REDACTED] [REDACTED] Rule may present an unreasonable risk of injury to the health of individuals exposed to the [REDACTED], the employees and workers involved in the manufacturing process at Inhance, and to the environment.

FIRST CLAIM FOR RELIEF
Declaratory Relief

52. Paragraphs 1 through 51 of the Complaint are incorporated herein by reference.

53. Pursuant to Section 5(a)(1) of TSCA, 15 U.S.C. § 2604(a)(1), no person may manufacture or process a chemical substance for a significant new use unless (1) that person submits a New Use Notice to the EPA, at least 90 days before such manufacture or processing; (2) the EPA reviews that notice; (3) the EPA makes a determination on that use under Section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3); and (4) the EPA “takes the actions required in association with that determination.”

54. The Defendant is a “person” under the regulations implementing TSCA. 40 C.F.R. § 720.3(x).

55. The Defendant is manufacturing or processing multiple [REDACTED] [REDACTED] Rule through its [REDACTED] activities for uses that the EPA has determined are significant new uses subject to the [REDACTED] Rule. [REDACTED].

56. The Defendant failed to submit to the [REDACTED], in accordance with Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), and 40 C.F.R. § 721.25, before manufacturing or processing [REDACTED] for a significant new use subject to the [REDACTED] Rule, of its intention to manufacture or process [REDACTED] for a significant new use subject to the [REDACTED] Rule.

57. The EPA has not issued determinations on the [REDACTED] by the Defendant, as required by Section 5(a)(1)(B) of TSCA, prior to Defendant manufacturing or processing [REDACTED] for a significant new use subject to the [REDACTED] Rule.

58. Because the EPA has not issued determinations on the [REDACTED] before the Defendant’s manufacturing or processing of [REDACTED] for a significant new use subject to the [REDACTED] Rule, the EPA has been denied the opportunity to conduct the review and

determination process before the Defendant's significant new uses of [REDACTED]

[REDACTED] Rule, as required by Section 5(a)(3) of TSCA. 15 U.S.C. § 2604(a)(3).

59. Pursuant to Section 15 of TSCA, 15 U.S.C. § 2614, it is unlawful for the Defendant to: (1) fail or refuse to comply with any requirement of TSCA or any rule promulgated under TSCA; (2) use for commercial purposes a chemical substance that such person knew or had reason to know was manufactured or processed in violation of Section 5, 15 U.S.C. § 2604; or (3) fail or refuse to submit notices as required by TSCA or any rule promulgated thereunder.

60. Under 40 C.F.R. § 721.35, it is a violation of Section 15 of TSCA, 15 U.S.C. § 2614, to fail to comply with any provision of Title 40, Part 721 of the regulations implementing TSCA.

61. An actual controversy exists between the United States and the Defendant. Pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, the United States is entitled to a declaratory judgment that the Defendant has and continues to violate Section 15 of TSCA, 15 U.S.C. § 2614, by failing or refusing to comply with Section 5 of TSCA, 15 U.S.C. § 2604, and all applicable regulatory requirements, by manufacturing or processing [REDACTED] for a significant new use subject to the [REDACTED] Rule, before submitting notices to the EPA, and before the EPA has conducted the review and determination process required under Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), and all applicable regulatory requirements.

SECOND CLAIM FOR RELIEF
Injunctive Relief

62. Paragraphs 1 through 51 of the Complaint are incorporated herein by reference.

63. Pursuant to Section 5(a)(1) of TSCA, 15 U.S.C. § 2604(a)(1), no person may manufacture or process a chemical substance for a significant new use unless (1) that person

submits a New Use Notice to the EPA, at least 90 days before such manufacture or processing, (2) the EPA reviews that notice, (3) the EPA makes a determination on that use under Section 5(a)(3) of TSCA, 15 U.S.C. § 2604(a)(3), and (4) the EPA “takes the actions required in association with that determination.”

64. The Defendant is a “person” under the regulations implementing TSCA. 40 C.F.R. § 720.3(x).

65. The Defendant is manufacturing or processing multiple [REDACTED] subject to the [REDACTED] Rule through its [REDACTED] activities for uses that the EPA has determined are significant new uses subject to the [REDACTED] Rule. [REDACTED].

66. The Defendant failed to submit to the [REDACTED], in accordance with Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), and 40 C.F.R. § 721.25, before manufacturing or processing [REDACTED] for a significant new use subject to the [REDACTED] Rule, of its intention to manufacture or process [REDACTED] for a significant new use subject to the [REDACTED] Rule.

67. The EPA has not issued determinations on the [REDACTED] by the Defendant, as required by Section 5(a)(1)(B) of TSCA, prior to Defendant manufacturing or processing [REDACTED] for a significant new use subject to the [REDACTED] Rule.

68. Because the EPA has not issued determinations on the [REDACTED] before the Defendant’s manufacturing or processing of [REDACTED] for a significant new use subject to the [REDACTED] Rule, the EPA has been denied the opportunity to conduct the review and determination process before the Defendant’s significant new uses of [REDACTED] subject to the [REDACTED] Rule, as required by Section 5(a)(3) of TSCA. 15 U.S.C. § 2604(a)(3).

69. Pursuant to Section 15 of TSCA, 15 U.S.C. § 2614, it is unlawful for the Defendant to: (1) fail or refuse to comply with any requirement of TSCA or any rule promulgated under TSCA; (2) use for commercial purposes a chemical substance which such person knew or had reason to know was manufactured or processed in violation of Section 5, 15 U.S.C. § 2604; or (3) fail or refuse to submit notices as required by TSCA or any rule promulgated thereunder.

70. Under 40 C.F.R. § 721.35, it is a violation of Section 15 of TSCA, 15 U.S.C. § 2614, to fail to comply with any provision of Title 40, Part 721 of the regulations implementing TSCA.

71. Inhance's past and continuing manufacture of [REDACTED] for a significant new use subject to the [REDACTED] Rule may present an unreasonable risk of injury to the health of individuals exposed to its products, the employees and workers involved in the manufacturing process at Inhance, and the environment.

72. Pursuant to Section 17 of TSCA, 15 U.S.C. § 2616, the Defendant should be: (A) restrained from violating Section 15 of TSCA, 15 U.S.C. § 2614; (B) restrained from the manufacture or processing of [REDACTED] for a significant new use subject to the [REDACTED] Rule, until the EPA has conducted the review and determination process required under Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B); and (C) directed to give notice of its manufacturing in violation of Section 5 of TSCA, 15 U.S.C. § 2604, to distributors in commerce of the [REDACTED] subject to the [REDACTED] Rule that it has produced for a significant new use, and, to the extent reasonably ascertainable, to other persons in possession of such [REDACTED] or exposed to such [REDACTED].

RELIEF SOUGHT

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Enter a declaratory judgment that the Defendant has and continues to violate Section 15 of TSCA, 15 U.S.C. 2614, by failing or refusing to comply with Section 5 of TSCA, 15 U.S.C. § 2604, and all applicable regulatory requirements, by manufacturing or processing ██████ for a significant new use subject to the ██████ Rule, before submitting a notice to the EPA, and before the EPA has conducted the review and determination process required under Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), and all applicable regulatory requirements.

B. Award the United States injunctive relief to: (A) restrain the Defendant from any violation of Section 15 of TSCA, 15 U.S.C. § 2614; (B) restrain the Defendant from the manufacture or processing of ██████ for a significant new use subject to the ██████ Rule, except in compliance with TSCA; and (C) direct the Defendant to give notice of its manufacturing in violation of Section 5 of TSCA, 15 U.S.C. § 2604, to distributors in commerce of the ██████ subject to the ██████ Rule that it has produced for a significant new use, and, to the extent reasonably ascertainable, to other persons in possession of such ██████ or exposed to such ██████.

C. Order the Defendant to take other appropriate actions to remedy, mitigate, and offset the harm to public health and the environment caused by the violations of TSCA alleged above;

D. Award Plaintiff its costs of this action; and

E. Grant such other relief as this Court may deem just and proper.

Respectfully submitted,

FOR THE UNITED STATES OF AMERICA

TODD KIM

Assistant Attorney General
Environment and Natural Resources Division
United States Department of Justice

Dated: December 19, 2022

/s/ Richard Gladstein

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Dated: December 19, 2022

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