

ENVIRONMENTAL APPEALS BOARD
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.

<p style="text-align: center;">In re Cytonix, LLC</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>Docket No. TSCA-HQ-2025-5003</p>
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FINAL ORDER

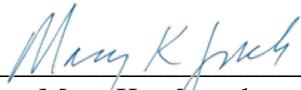
Pursuant to 40 C.F.R. § 22.18(b)-(c) of EPA’s Consolidated Rules of Practice, the attached Consent Agreement resolving this matter is incorporated by reference into this Final Order and is hereby ratified.

The Respondent is ORDERED to comply with all terms of the Consent Agreement, effective immediately.

So ordered.¹

ENVIRONMENTAL APPEALS BOARD

Dated: May 5, 2025



 Mary Kay Lynch
 Environmental Appeals Judge

¹ The three-member panel ratifying this matter is composed of Environmental Appeals Judges Aaron P. Avila, Wendy L. Blake, and Mary Kay Lynch.

**BEFORE THE ENVIRONMENTAL APPEALS BOARD UNITED
STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.**

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<i>In the Matter of:</i>)	
)	
Cytonix, LLC)	
Silver Spring, MD)	
)	Docket No. TSCA-HQ-2025-5003
)	
Respondent)	
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CONSENT AGREEMENT

Complainant, United States Environmental Protection Agency (hereinafter, “EPA” or “Agency”), and Respondent, Cytonix, LLC (“Cytonix”) (collectively, the “Parties”), hereby enter into this Consent Agreement and proposed Final Order before the taking of any testimony and without adjudicating of any issues of law or fact, consent to the terms of this Consent Agreement and attached Final Order.

PRELIMINARY STATEMENT

1. This civil administrative proceeding for the assessment of penalties pursuant to section 16(a) of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2615(a), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, June 22, 2016, 130 Stat 448 (2016 Act), is being simultaneously commenced and concluded pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, and the Revocation, Termination or Suspension of Permits (“Consolidated Rules”), 40 C.F.R. Part 22.
2. On August 4, 2022, EPA inspectors discovered Respondent’s potential noncompliance with TSCA requirements for a manufactured chemical substance consisting of short-chain polyfluorinated materials, which was developed as a replacement for a chemical substance containing long-chain (C8) perfluorinated alkyl groups. Respondent has claimed the identity of the chemical as TSCA confidential business information (CBI), which is herein referred to as Chemical A.
3. On or about May 9, 2024, EPA sent a Notice of Violation, Opportunity to Show Cause letter (hereinafter, Show Cause Letter) to Respondent, which identified potential TSCA Section 5

violations for manufacturing Chemical A prior to submitting a Pre-manufacture Notice (PMN) or an applicable exemption application.

4. In a June 28, 2024 response to the Show Cause Letter, Respondent explained that they mistakenly believed the chemical substance to be included on the TSCA Inventory at the time of the illegal manufacture. Respondent also indicated therein that they had immediately ceased manufacturing and quarantined all of their existing stocks of Chemical A as soon as they learned of the illegal manufacture, which was on or about the August 4, 2022 EPA inspection date.
5. Subsequently, during a September 4, 2024 conference call, Respondent stated that they do not intend to process or use their quarantined existing stocks of Chemical A, but instead, seek to only dispose them.
6. The Parties' discussions have resulted in the agreement contained herein, which includes terms for the disposal of Respondent's quarantined existing stocks of Chemical A.
7. To avoid the disruption of orderly business activities and the expense of protracted and costly litigation, Respondent, for purposes of this proceeding only and as required by 40 C.F.R. § 22.18(b)(2):

- a. admits the following jurisdictional allegations and waives any defenses to jurisdiction:
 - i. Respondent is a corporation located at 12401 Prosperity Drive, Silver Spring MD, 20904 and is a "person" as defined in 40 C.F.R. § 720.3(x) and, as such, is subject to TSCA and its regulations; and
 - ii. Respondent manufactures, processes, or distributes in commerce, a chemical substance identified as Chemical A or mixtures containing this chemical, or in the past has manufactured, processed, or distributed in commerce Chemical A or mixtures containing this chemical as those terms are defined in sections 3(2), (5), (9), (10), and (13) of TSCA, 15 U.S.C. § 2602(2), (5), (9), (10), and (13) respectively, and 40 C.F.R. § 720.3(e), (i), (q), (u), and (aa). Respondent is subject to TSCA, and the regulations promulgated thereunder.
- b. neither admits nor denies the specific factual allegations contained herein;
- c. consents to the assessment of a civil penalty on the terms discussed below;
- d. consents to any conditions specified in this Consent Agreement;
- e. waives any right to contest the alleged violations of law set forth herein; and

- f. waives the rights to appeal the proposed Final Order accompanying this Consent Agreement.
8. By signing this consent agreement, respondent waives any rights or defenses that respondent has or may have for this matter to be resolved in federal court, including but not limited to any right to a jury trial, and waives any right to challenge the lawfulness of the final order accompanying the consent agreement.

II. EPA'S FINDINGS OF FACT AND LAW

COUNT I – TSCA § 5(a)(1) VIOLATION

9. Any chemical substance that is not included in the chemical substance list compiled and published under section 8(b) of TSCA, 15 U.S.C. § 2607(b) (“TSCA Inventory”), is a “new chemical substance,” as defined under section 3(11) of TSCA, 15 U.S.C. § 2602(11) and 40 C.F.R. § 720.3(v).
10. Section 5(a)(1) of TSCA, 15 U.S.C. § 2604(a)(1), and 40 C.F.R. §§ 720.22(a)(1) and 720.40(b), provide that no person may manufacture (including import) a new chemical substance unless such person submits a PMN to EPA at least ninety (90) calendar days before manufacturing that substance.
11. Per the Low Volume Exemption (“LVE”) under 40 C.F.R. § 723.50(e)(1), an applicant must submit to EPA an exemption application on EPA Form No. 7710-25 via CDX using e-PMN software in the manner set forth in this paragraph at least thirty (30) days before the manufacture of the new chemical substance begins.
12. Based on the information obtained during the EPA’s August 4, 2022 inspection and subsequent to the inspection, EPA found that Respondent had manufactured Chemical A on at least 77 occasions (with relevant dates and quantities claimed as CBI) prior to submitting a PMN or an applicable LVE application for this Chemical.
13. Respondent filed a LVE application for Chemical A on September 21, 2022.
14. Chemical A was not included on the TSCA Inventory at the time of manufacture, and therefore, is a “new chemical substance” as defined under section 3(11) of TSCA, 15 U.S.C. § 2602(11) and 40 C.F.R. § 720.3(v).
15. Respondent’s failure to submit either a PMN application at least ninety (90) days before or an applicable LVE application at least thirty (30) days before manufacturing Chemical A constitutes a failure to comply with section 5 of TSCA, 15 U.S.C. § 2604, which is a prohibited act under section 15(1) of TSCA, 15 U.S.C. § 2614(1), and may subject an entity to civil penalties pursuant to section 16(a) of TSCA, 15 U.S.C. § 2615(a).

III. CIVIL PENALTY

16. Pursuant to Section 16 of TSCA, 15 U.S.C. § 2615, and taking into account the relevant statutory penalty criteria, the applicable penalty policies, and other relevant factors, Respondent agrees to pay a civil penalty in the amount of ONE HUNDRED AND NINETY THOUSAND, FIVE HUNDRED AND TWENTY FIVE DOLLARS (\$190,525) for the alleged violations identified herein within thirty (30) days after the date the Final Order ratifying this Agreement is filed with the Clerk of the Environmental Appeals Board (“Effective Date”).
17. Respondent shall pay the Assessed Penalty and any interest, fees, and other charges due using any method, or combination of appropriate methods, as provided on EPA websites: <https://www.epa.gov/financial/makepayment> and <https://www.epa.gov/financial/additional-instructions-making-payments-epa>.
18. When making a payment, Respondent shall:
- Identify every payment with Respondent’s name and the docket number of this Agreement, TSCA-HQ-2025-5003.
 - Concurrently with any payment or within 24 hours of any payment, Respondent shall serve proof of such payment to the following person(s):

Emilio Cortes
Clerk of the Board
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Valarie Franklyn, Environmental Engineer
1200 Pennsylvania Avenue, NW
Washington, DC 20460
franklyn.valarie@epa.gov

and

U.S. Environmental Protection Agency
Cincinnati Finance Center
Via electronic mail to:
CINWD_AcctsReceivable@epa.gov

“Proof of payment” means, as applicable, a copy of the check, confirmation of credit card or debit card payment, or confirmation of wire or automated clearinghouse

transfer, and any other information required to demonstrate that payment has been made according to EPA requirements, in the amount due, and identified with the appropriate docket number and Respondent's name.

19. Interest, Charges, and Penalties on Late Payments. Pursuant to 15 U.S.C. § 2615, 31 U.S.C. § 3717, 31 C.F.R. § 901.9, and 40 C.F.R. § 13.11, if Respondent fails to timely pay any portion of the Assessed Penalty per this Agreement, the entire unpaid balance of the Assessed Penalty and all accrued interest shall become immediately due and owing, and EPA is authorized to recover the following amounts.

- a. Interest. Interest begins to accrue from the Filing Date. If the Assessed Penalty is paid in full within thirty (30) days, interest accrued is waived. If the Assessed Penalty is not paid in full within thirty (30) days, interest will continue to accrue until any unpaid portion of the Assessed Penalty as well as any interest, penalties, and other charges are paid in full. To protect the interests of the United States the rate of interest is set at the IRS standard underpayment rate, any lower rate would fail to provide Respondent adequate incentive for timely payment.
- b. Handling Charges. Respondent will be assessed monthly a charge to cover EPA's costs of processing and handling overdue debts. If Respondent fails to pay the Assessed Penalty in accordance with this Agreement, EPA will assess a charge to cover the costs of handling any unpaid amounts for the first thirty (30) day period after the Filing Date. Additional handling charges will be assessed each subsequent thirty (30) days, or any portion thereof, until the unpaid portion of the Assessed Penalty, as well as any accrued interest, penalties, and other charges are paid in full.
- c. Late Payment Penalty. A late payment penalty of six percent (6%) per annum, will be assessed monthly on all debts, including any unpaid portion of the Assessed Penalty, interest, and other charges, that remain delinquent more than ninety (90) days.

20. Late Penalty Actions. In addition to the amounts described in the prior Paragraph, if Respondent fails to timely pay any portion of the Assessed Penalty, interest, or other charges and penalties per this Agreement, EPA may take additional actions. Such actions may include, but are not limited to, the following.

- a. Refer the debt to a credit reporting agency or a collection agency, per 40 C.F.R. §§ 13.13 and 13.14.
- b. Collect the debt by administrative offset (i.e., the withholding of money payable by the United States government to, or held by the United States government for, a person to satisfy the debt the person owes the United States government), which includes, but is not limited to, referral to the Internal Revenue Service for offset against income tax refunds, 40 C.F.R. Part 13, Subparts C and H.

- c. Suspend or revoke Respondent's licenses or other privileges, or suspend or disqualify Respondent from doing business with EPA or engaging in programs EPA sponsors or funds, 40 C.F.R. § 13.17.
 - d. Per 15 U.S.C. § 2615(a), the Attorney General will bring a civil action in the appropriate district court to recover the full remaining balance of the debt plus interest. In such an action, the validity, amount, and appropriateness of the Assessed Penalty shall not be subject to review.
21. Allocation of Payments. Pursuant to 31 C.F.R. § 901.9(f) and 40 C.F.R. § 13.11(d), a partial payment of debt will be applied first to outstanding handling charges, second to late penalty charges, third to accrued interest, and last to the principal that is the outstanding Assessed Penalty amount.
22. Tax Treatment of Penalties. Penalties, interest, and other charges paid pursuant to this Agreement shall not be deductible for purposes of federal taxes.
23. Pursuant to 26 U.S.C. § 6050X and 26 C.F.R. § 1.6050X-1, EPA is required to send to the Internal Revenue Service ("IRS") annually, a completed IRS Form 1098-F ("Fines, Penalties, and Other Amounts") with respect to any court order or settlement agreement (including administrative settlements), that require a payor to pay an aggregate amount that EPA reasonably believes will be equal to, or in excess of, \$50,000 for the payor's violation of any law or the investigation or inquiry into the payor's potential violation of any law, including amounts paid for "restitution or remediation of property" or to come "into compliance with a law." EPA is further required to furnish a written statement, which provides the same information provided to the IRS, to each payor (i.e., a copy of IRS Form 1098-F). Failure to comply with providing IRS Form W-9 or Tax Identification Number ("TIN"), as described below, may subject Respondent to a penalty, per 26 U.S.C. § 6723, 26 U.S.C. § 6724(d)(3), and 26 C.F.R. § 301.6723-1. In order to provide EPA with sufficient information to enable it to fulfill these obligations, EPA herein requires, and Respondent herein agrees, that:
- a. Respondent shall complete an IRS Form W-9 ("Request for Taxpayer Identification Number and Certification"), which is available at <https://www.irs.gov/pub/irs-pdf/fw9.pdf>;
 - b. Respondent shall therein certify that its completed IRS Form W-9 includes Respondent's correct TIN or that Respondent has applied and is waiting for issuance of a TIN;
 - c. Respondent shall email its completed Form W-9 to EPA's Cincinnati Finance Center to Milton Wise at Wise.Milton@epa.gov, within 30 days after the Final Order ratifying this Agreement is filed, and EPA recommends encrypting IRS Form W-9 email correspondence; and
 - d. In the event that Respondent has certified in its completed IRS Form W-9 that it has applied for a TIN and that TIN has not been issued to Respondent within 30 days

after the Effective Date, then Respondent, using the same email address identified in the preceding sub-paragraph, shall further:

- i. notify EPA's Cincinnati Finance Center of this fact, via email, within 30 days after the 30 days after the Effective Date; and
- ii. provide EPA's Cincinnati Finance Center with Respondent's TIN, via email, within five (5) days of Respondent's issuance and receipt of the TIN.

24. For purposes of the identification requirement in Section 162(f)(2)(A)(ii) of the Internal Revenue Code, 26 U.S.C. § 162(f)(2)(A)(ii), and 26 C.F.R. § 1.162-21(b)(2), performance of the release of the quarantined existing stock of Chemical A, as set forth in paragraphs 27 through 29, is restitution, remediation, or required to come into compliance with the law.

IV. TERMS OF SETTLEMENT

25. Respondent's full compliance with this Consent Agreement shall only resolve Respondent's liability for federal civil penalties for the violations alleged in this Consent Agreement.

26. This settlement is conditioned upon the thoroughness and accuracy of Respondent's submissions to EPA in this matter.

27. As a condition of this Consent Agreement, Respondent shall consult the *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances-Version 2 (2024)* for analyzing disposal options of quarantined existing stocks of Chemical A that minimize potential environmental releases.

28. If the Respondent chooses to dispose of the existing quarantined stocks of Chemical A, the Company shall dispose of any unused portion of its existing stocks of Chemical A in accordance with applicable federal and state requirements. The Company should coordinate with the applicable state(s) where disposal may occur to determine if additional requirements or a preferred approach (e.g., incineration) should be considered before disposing Chemical A.

29. Respondent shall submit documentation showing compliance with the terms of settlement as set forth in Paragraphs 27 through 28 within 30 days of disposal of all existing quarantined stocks of Chemical A containing PFAS and specify the disposal method Respondent used.

30. Compliance with this CAFO shall not be a defense to any subsequent action EPA may commence pursuant to federal law or regulation for violations occurring after the date of this Consent Agreement, nor any violations of TSCA not alleged in this Consent Agreement that may have occurred prior to the date that this Consent Agreement is fully executed by both Parties.

31. Nothing in this Consent Agreement is intended to, nor shall be, construed to operate in any way to resolve any criminal liability of Respondent.
32. By executing this Consent Agreement, Respondent certifies that, to the best of its knowledge regarding the violations alleged herein, Respondent is in compliance with TSCA section 5 and 15 U.S.C. § 2604.

V. OTHER MATTERS

33. Subject to the terms and conditions herein, this Consent Agreement shall be binding upon the Parties, and their respective officers, directors, employees, successors, and assigns. The undersigned representative of each Party certifies that he or she is duly authorized by his or her respective Party to enter into this binding Consent Agreement.
34. This Consent Agreement shall take full effect upon the signing and filing of the Final Order by the EPA's Environmental Appeals Board (EAB).
35. This Consent Agreement may be amended or modified only by written agreement executed by both the EPA and Respondent.
36. Respondent's obligations under this Consent Agreement shall end when it has paid in full the scheduled civil penalty, paid any stipulated penalties, and submitted documentation required by the Consent Agreement and Final Order.
37. All of the terms and conditions of this Consent Agreement together comprise one settlement agreement, and each of the terms and conditions is in consideration for all of the other terms and conditions. This Consent Agreement shall be null and void if any term or condition of this Consent Agreement is held invalid or is not executed by all of the signatory parties in identical form or is not approved in such identical form by the EAB.
38. Failure of Respondent to remit the civil penalties provided herein will result in this matter being forwarded to the United States Department of Justice for collection.
39. The Parties agree to bear their own costs and attorney's fees.

WE HEREBY AGREE TO THIS:

Elaine Lanza
Elaine Lanza, Partner
Cytonix LLC
12410 Prosperity Drive
Silver Spring MD 20904

Date: March 10, 2025

WE HEREBY AGREE TO THIS:

**GREGORY
SULLIVAN** Digitally signed by
GREGORY
SULLIVAN
Date: 2025.03.19
10:54:31 -04'00'

Gregory Sullivan, Director
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
United States Environmental Protection Agency

**CATHERINE
LEE** Digitally signed by
CATHERINE LEE
Date: 2025.03.11
09:52:00 -04'00'

Catherine Lee, Attorney
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance
Assurance
United States Environmental Protection
Agency

CERTIFICATE OF SERVICE

I certify that copies of the foregoing “Consent Agreement” and “Final Order,” in the matter of Cytonix, LLC, Docket No. TSCA-HQ-2025-5003, were sent to the following persons in the manner indicated:

By E-mail:

Catherine Lee, Attorney
Waste and Chemical Enforcement Division
Office of Civil Enforcement
Office of Enforcement and Compliance Assurance
U.S. Environmental Protection Agency
Washington, DC 20460
Lee.catherine@epa.gov

Luke Ratnasinghe
Cytonix LLC
12410 Prosperity Drive
Silver Spring, MD 20904
Luke@cytonix.com

Dated: May 05, 2025

Annette Duncan

Annette Duncan
Administrative Specialist