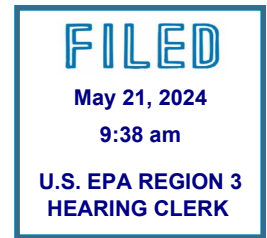


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103**



In the Matter of: :
:
:
TRINITY STERILE, INC. : U.S. EPA Docket No. EPCRA-03-2024-0107
201 KILEY DRIVE :
SALISBURY, MD 21801 : Proceeding under Section 325(c) of The
: Emergency Planning and Community Right-to-
Respondent. : Know Act, 42 U.S.C. § 11045(c)

CONSENT AGREEMENT

PRELIMINARY STATEMENT

1. This Consent Agreement is entered into by the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region 3 (“Complainant”) and Trinity Sterile, Inc. (“Respondent”) (collectively the “Parties”), pursuant to Section 325(c) of the Emergency Planning and Community Right-to-Know Act, 40 U.S.C. § 11045(c), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation, Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. Part 22. The Emergency Planning and Community Right-to-Know Act authorizes the Administrator of the U.S. Environmental Protection Agency to assess penalties and undertake other actions required by this Consent Agreement. The Administrator has delegated this authority to the Regional Administrator who, in turn, has delegated the authority to enter into agreements concerning administrative penalties to the Complainant. This Consent Agreement and the attached Final Order (hereinafter jointly referred to as the “Consent Agreement and Final Order”) resolve Complainant’s civil penalty claims against Respondent under the Emergency Planning and Community Right-to-Know Act (“EPCRA” or the “Act”) for the violations alleged herein.
2. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant hereby simultaneously commences and resolves this administrative proceeding.

JURISDICTION

3. The U.S. Environmental Protection Agency (“EPA”) has jurisdiction over the above-captioned matter, as described in Paragraph 1, above.

4. The Consolidated Rules of Practice govern this administrative adjudicatory proceeding pursuant to 40 C.F.R. § 22.1(a)(8).

GENERAL PROVISIONS

5. For purposes of this proceeding only, Respondent admits the jurisdictional allegations set forth in this Consent Agreement and Final Order.
6. Except as provided in Paragraph 5, above, Respondent neither admits nor denies the specific factual allegations set forth in this Consent Agreement.
7. Respondent agrees not to contest the jurisdiction of the EPA with respect to the execution of this Consent Agreement, the issuance of the attached Final Order, or the enforcement of this Consent Agreement and Final Order.
8. For purposes of this proceeding only, Respondent hereby expressly waives its right to contest the allegations set forth in **this Consent Agreement and Final Order** and waives its right to appeal the accompanying Final Order.
9. Respondent consents to the assessment of the civil penalty stated herein, to the issuance of any specified compliance order herein, and to any conditions specified herein.
10. Respondent shall bear its own costs and attorney's fees in connection with this proceeding.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

11. In accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, Complainant alleges and adopts the Findings of Fact and Conclusions of Law set forth immediately below.
12. Respondent assembles, sterilizes, and sells medical kits, procedure trays, and a wide range of disposable or reusable medical supplies. Respondent's operations include staging, pre-conditioning, degassing, and sterilization by using ethylene oxide as an agent, and outgoing shipment.
13. Respondent is, and at all times relevant to the violations alleged herein, was, a foreign business incorporated in the state of Florida and registered in the state of Maryland.
14. Respondent is a "person" as that term is defined in Section 329(7) of EPCRA, 42 U.S.C. § 11049(7) and is subject to the assessment of civil penalties for the violations alleged herein.

15. Respondent is and, at all times relevant to the violations alleged herein, was the owner and operator of a “facility”, as that term is defined in Section 329(4) of EPCRA, 42 U.S.C. § 11049(4), located at 201 Kiley Drive, Salisbury, MD (hereinafter “the Facility”).
16. On December 23, 2021, Respondent was notified by the EPA Office of Chemical Safety and Pollution Prevention Branch that moving forward, the Facility was subject to the reporting and recordkeeping requirements of Section 313(a) of EPCRA pursuant to a December 16, 2021 determination made by the EPA Administrator pursuant to Section 313(b)(2) of EPCRA, 42 U.S.C. § 11023(b)(2).
17. On December 4, 2023, the EPA sent Respondent a request for information related to Respondent’s compliance with Section 313 of EPCRA, 42 U.S.C. § 11023, and the regulations codified at 40 C.F.R. Part 372, Subpart B (Reporting Requirements).
18. On December 13, 2023, Respondent responded to the EPA’s request for information.
19. On March 15, 2024, the EPA issued a Notice of Potential Violation and Opportunity to Confer (“NOPVOC”) letter to Respondent.
20. On March 27, 2024, Respondent sent a letter via email in response to the alleged violations in the NOPVOC.
21. On April 22, 2024, the parties participated in an Opportunity to Confer conference.

Count I

Failure to Report Toxic Chemical Release Form for Ethyl Oxide for Calendar Year 2022

22. The information and allegations in the preceding paragraphs of this Consent Agreement are incorporated herein by reference.
23. Section 313(a) of EPCRA, 42 U.S.C. § 11023(a) requires that “[t]he owner or operator of a facility subject to the requirements of this section shall complete a toxic chemical release form as published under subsection (g) for each toxic chemical listed under subsection (c) that was manufactured, processed, or otherwise used in quantities exceeding the toxic chemical threshold quantity established by subsection (f) during the preceding calendar year at such facility.” *See also* 40 C.F.R. § 372.30.
24. Pursuant to Section 313(b)(1)(A) of EPCRA, 42 U.S.C. § 11023(b)(1)(A), the requirements of Section 313 “apply to owners and operators of facilities that have 10 or more full-time employees and that are in Standard Industrial Classification Codes 20 through 39 (as in effect on July 1, 1985) and that manufactured, processed, or otherwise used a toxic chemical listed under subsection (c) in excess of the quantity of that toxic

chemical established under subsection (f) during the calendar year for which a release form is required under this section.” *See also* 40 C.F.R. § 372.22.

25. Pursuant to Section 313(b)(2) of EPCRA, 42 U.S.C. § 11023(b)(2), the Administrator “may apply the requirements of this section to the owners and operators of any particular facility that manufactures, processes, or otherwise uses a toxic chemical listed under subsection (c) if the Administrator determines that such action is warranted on the basis of toxicity of the toxic chemical, proximity to other facilities that release the toxic chemical or to population centers, the history of releases of such chemical at such facility, or such other factors as the Administrator deems appropriate.”
26. On December 16, 2021, the EPA Administrator made a determination pursuant to Section 313(b)(2) of EPCRA, 42 U.S.C. § 11023(b)(2), to extend the reporting requirements for ethylene oxide releases and other waste management activities to certain contract sterilization facilities. *See* Determination of the Administrator of the Environmental Protection Agency Under the Emergency Planning and Community Right-to-Know Act Section 313(b)(2) to Apply the Requirements of EPCRA Section 313 to Certain Contract Sterilization Facilities, EPA-HQ-OPPT-2021-0693-0002; *see also* 86 Fed. Reg. 73764 (Dec. 21, 2021).
27. Respondent’s facility was included in the list of facilities required to comply with the reporting requirements for pursuant to the December 16, 2021 determination made by the Administrator. *See* EPA-HQ-OPPT-2021-0693-0002, App. A, p. 53; *see also* 86 Fed. Reg. 73764, 73765.
28. Each toxic chemical release form (“TRI Form”) must be submitted on or before July 1 of the next year. 40 C.F.R. § 372.30(d).
29. 40 C.F.R. § 372.65 lists the chemicals and chemical categories to which the regulations promulgated pursuant to EPCRA, apply.
30. Pursuant to 40 C.F.R. § 372.65(1), Table 1, ethylene oxide is a regulated chemical.
31. During calendar year 2022, Respondent had approximately 97 full time employees.
32. During calendar year 2022, Respondent otherwise used approximately 20,315 lbs. of ethylene oxide.
33. On July 20, 2023, Respondent submitted a TRI Form for ethylene oxide for calendar year 2022.
34. For calendar year 2022, Respondent failed to submit a TRI Form for ethylene oxide by the July 1, 2023 reporting deadline.

35. For calendar year 2022, Respondent violated 40 C.F.R. § 372.30 by failing to timely report the amounts of the toxic chemical ethylene oxide released from the Facility by July 1, of the year following the release.
36. In failing to comply with 40 C.F.R. § 372.30, Respondent is in violation of Section 313 of EPCRA, 42 U.S.C. § 11023, and is subject to the assessment of penalties under Section 325(c) of EPCRA, 42 U.S.C. § 11045(c).

CIVIL PENALTY

37. In settlement of the EPA's claims for civil penalties for the violations alleged in this Consent Agreement, Respondent consents to the assessment of a civil penalty in the amount of Eight Thousand, Six Hundred and Eighty-Eight dollars (\$8,688), which Respondent shall be liable to pay in accordance with the terms set forth below.
38. The civil penalty is based upon the EPA's consideration of a number of factors. These factors were applied to the particular facts and circumstances of this case with specific reference to the EPA's *Enforcement Response Policy for Section 313 of the Emergency Planning and Community Right to Know Act (1987) and Section 6607 of the Pollution Prevention Act (1990)*, Feb. 24, 2017 (amended), the appropriate *Adjustment of Civil Monetary Penalties for Inflation*, pursuant to 40 C.F.R. Part 19, and the applicable EPA memoranda addressing the EPA's civil penalty policies to account for inflation.
39. Respondent agrees to pay a civil penalty in the amount of \$8,688 ("Assessed Penalty") within thirty (30) days of the Effective Date of this Consent Agreement and Final Order.
40. 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 the EPA website: <https://www.epa.gov/financial/makepayment>. For additional instructions see: <https://www.epa.gov/financial/additional-instructions-making-payments-epa>.
41. When making a payment, Respondent shall:
 - a. Identify every payment with Respondent's name and the docket number of this Consent Agreement, **EPCRA-03-2024-0107**,
 - b. Concurrently with any payment or within 24 hours of any payment, Respondent shall serve Proof of Payment simultaneously **by email** to the following person(s):

Hannah Leone
Assistant Regional Counsel
Leone.hannah@epa.gov,

U.S. Environmental Protection Agency
Cincinnati Finance Center
CINWD_AcctsReceivable@epa.gov

and

U.S. EPA Region 3 Regional Hearing Clerk
R3_Hearing_Clerk@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 the EPA requirements, in the amount due, and identified with the appropriate docket number and Respondent’s name.

42. Interest, Charges, and Penalties on Late Payments. Pursuant to 31 U.S.C. § 3717, 31 C.F.R. § 901.9, and 40 C.F.R. § 13.11, if Respondent fails to timely pay the full amount of the Assessed Penalty per this Consent Agreement, the EPA is authorized to recover, in addition to the amount of the unpaid Assessed Penalty, the following amounts.

a. Interest. Interest begins to accrue from the Effective Date of this Consent Agreement. 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 Consent Agreement, the EPA will assess a charge to cover the costs of handling any unpaid amounts for the first thirty (30) day period after the Effective Date. Additional handling charges will be assessed every 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, penalties, and other charges, that remain delinquent more than ninety (90) days. Any such amounts will accrue from the Effective Date.

43. 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 Consent Agreement, the EPA may take additional actions. Such actions EPA may take 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, per 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 the EPA or engaging in programs the EPA sponsors or funds, per 40 C.F.R. § 13.17.
 - d. Refer this matter to the United States Department of Justice for litigation and collection, per 40 C.F.R. § 13.33.
44. 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.
45. Tax Treatment of Penalties. Penalties, interest, and other charges paid pursuant to this Consent Agreement shall not be deductible for purposes of federal taxes.
46. Payment of the civil penalty is due and payable immediately upon receipt by Respondent of a true and correct copy of the fully executed and filed Consent Agreement and Final Order. Receipt by Respondent or Respondent's legal counsel of such copy of the fully executed Consent Agreement and Final Order, with a date stamp indicating the date on which the Consent Agreement and Final Order was filed with the Regional Hearing Clerk, shall constitute receipt of written initial notice that a debt is owed the EPA by Respondent in accordance with 40 C.F.R. § 13.9(a).
47. Failure by the Respondent to pay the EPCRA civil penalty assessed by the Final Order in accordance with the terms of this Consent Agreement and Final Order may subject Respondent to a civil action to collect the assessed penalties, plus interest, pursuant to Section 325 of EPCRA, 42 U.S.C. § 11045. In any such collection action, the validity, amount and appropriateness of the penalty shall not be subject to review.

48. The parties consent to service of the Final Order by e-mail at the following valid email addresses: leone.hannah@epa.gov (for Complainant), and jennifer.adams@hoganlovells.com (for Respondent).

GENERAL SETTLEMENT CONDITIONS

49. By signing this Consent Agreement, Respondent acknowledges that this Consent Agreement and Final Order will be available to the public and represents that, to the best of Respondent's knowledge and belief, this Consent Agreement and Final Order does not contain any confidential business information or personally identifiable information from Respondent.
50. Respondent certifies that any information or representation it has supplied or made to the EPA concerning this matter was, at the time of submission true, accurate, and complete and that there has been no material change regarding the truthfulness, accuracy or completeness of such information or representation. The EPA shall have the right to institute further actions to recover appropriate relief if the EPA obtains evidence that any information provided and/or representations made by Respondent to the EPA regarding matters relevant to this Consent Agreement and Final Order, including information about respondent's ability to pay a penalty, are false or, in any material respect, inaccurate. This right shall be in addition to all other rights and causes of action that the EPA may have, civil or criminal, under law or equity in such event. Respondent and its officers, directors and agents are aware that the submission of false or misleading information to the United States government may subject a person to separate civil and/or criminal liability.
51. Respondent certifies to the EPA, upon personal investigation and to the best of its knowledge and belief, that it currently is in compliance with regard to the violations alleged in this Consent Agreement.

OTHER APPLICABLE LAWS

52. Nothing in this Consent Agreement and Final Order shall relieve Respondent of its obligation to comply with all applicable federal, state, and local laws and regulations, nor shall it restrict the EPA's authority to seek compliance with any applicable laws or regulations, nor shall it be construed to be a ruling on the validity of any federal, state or local permit. This Consent Agreement and Final Order does not constitute a waiver, suspension or modification of the requirements of EPCRA, or any regulations promulgated thereunder.

RESERVATION OF RIGHTS

53. This Consent Agreement and Final Order resolves only the EPA’s claims for civil penalties for the specific violations alleged against Respondent in this Consent Agreement and Final Order. The EPA reserves the right to commence action against any person, including Respondent, in response to any condition which the EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. This settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Section 22.18(c) of the Consolidated Rules of Practice, 40 C.F.R. § 22.18(c). The EPA reserves any rights and remedies available to it under EPCRA the regulations promulgated thereunder and any other federal law or regulation to enforce the terms of this Consent Agreement and Final Order after its effective date.

EXECUTION /PARTIES BOUND

54. This Consent Agreement and Final Order shall apply to and be binding upon the EPA, the Respondent and the officers, directors, employees, contractors, successors, agents and assigns of Respondent. By his or her signature below, the person who signs this Consent Agreement on behalf of Respondent is acknowledging that he or she is fully authorized by the Respondent to execute this Consent Agreement and to legally bind Respondent to the terms and conditions of this Consent Agreement and Final Order.

EFFECTIVE DATE

55. The effective date of this Consent Agreement and Final Order (“Effective Date”) is the date on which the Final Order, signed by the Regional Administrator of the EPA, Region 3, or his/her designee, the Regional Judicial Officer, is filed along with the Consent Agreement with the Regional Hearing Clerk pursuant to the Consolidated Rules of Practice.

ENTIRE AGREEMENT

56. This Consent Agreement and Final Order constitutes the entire agreement and understanding between the Parties regarding settlement of all claims for civil penalties pertaining to the specific violations alleged herein and there are no representations, warranties, covenants, terms, or conditions agreed upon between the Parties other than those expressed in this Consent Agreement and Final Order.

In the Matter of: Trinity Sterile, Inc.

EPA Docket No. EPCRA-03-2024-0107

For Respondent: Trinity Sterile, Inc.

Date: _____

By: _____

Abrar Solatch
President

For the Complainant:

After reviewing the Consent Agreement and other pertinent matters, I, the undersigned Director of the Enforcement & Compliance Assurance Division of the United States Environmental Protection Agency, Region 3, agree to the terms and conditions of this Consent Agreement and recommend that the Regional Administrator, or his/her designee, the Regional Judicial Officer, issue the attached Final Order.

By: _____

[Digital Signature and Date]

Karen Melvin, Director

Enforcement & Compliance Assurance Division

U.S. EPA – Region 3

Complainant

Attorney for Complainant:

By: _____

[Digital Signature and Date]

Hannah Leone

Assistant Regional Counsel

U.S. EPA – Region 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103



In the Matter of: :
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TRINITY STERILE, INC. : U.S. EPA Docket No. EPCRA-03-2024-0107
201 KILEY DRIVE : :
SALISBURY, MD 21801 : Proceeding under Section 325(c) of The
Respondent. : Emergency Planning and Community Right-to-
: Know Act, 42 U.S.C. § 11045(c)

FINAL ORDER

Complainant, the Director of the Enforcement and Compliance Assurance Division, U.S. Environmental Protection Agency, Region 3, and Respondent, Trinity Sterile, Inc. have executed a document entitled "Consent Agreement," which I hereby ratify as a Consent Agreement in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits ("Consolidated Rules of Practice"), 40 C.F.R. Part 22, Sections 22.13(b) and 22.18(b)(2) and (3). The terms of the foregoing Consent Agreement are accepted by the undersigned and incorporated into this Final Order as if fully set forth at length herein.

Based upon the representations of the parties in the attached Consent Agreement, the penalty agreed to therein is based upon consideration of, *inter alia*, the EPA's *Enforcement Response Policy for Section 313 of the Emergency Planning and Community Right to Know Act (1987) and Section 6607 of the Pollution Prevention Act (1990)*, Feb. 24, 2017 (amended).

NOW, THEREFORE, PURSUANT TO Section 325(c) of the Emergency Planning and Community Right-to-Know Act, 42 U.S.C. § 11045(c), and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondent pay a civil penalty in the amount of ***Eight Thousand, Six Hundred and Eighty-Eight dollars (\$8,688)***, in accordance with the payment provisions set forth in the Consent Agreement and in 40 C.F.R. § 22.31(c), and comply with the terms and conditions of the Consent Agreement.

This Final Order constitutes the final Agency action in this proceeding. This Final Order 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 the law. This Final Order resolves only those causes of action alleged in the Consent Agreement and does not waive, extinguish or otherwise affect Respondent's obligation to comply with all applicable provisions of the Emergency Planning and Community Right-to-Know Act and the regulations promulgated thereunder.

The effective date of the attached Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

By: _____
Joseph J. Lisa
Regional Judicial and Presiding Officer
U.S. EPA Region 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 3
Philadelphia, Pennsylvania 19103

In the Matter of:	:	
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TRINITY STERILE, INC.	:	
201 KILEY DRIVE	:	U.S. EPA Docket No. EPCRA-03-2024-0107
SALISBURY, MD 21801	:	
	:	Proceeding under Section 325(c) of the
Respondent.	:	Emergency Planning and Community Right-
	:	to-Know Act

CERTIFICATE OF SERVICE

I certify that the foregoing ***Consent Agreement and Final Order*** was filed with the EPA Region 3 Regional Hearing Clerk on the date that has been electronically stamped on the ***Consent Agreement and Final Order***. I further certify that on the date set forth below, I caused to be served a true and correct copy of the foregoing to each of the following persons, in the manner specified below, at the following addresses:

Copies served via email to:

Abrar Solatch, President
Trinity Sterile, Inc.
Abrar.Solatch@trinitysterile.com
201 Kiley Drive
Salisbury, MD 21801

Jennifer Adams
Hogan Lovells US LLP
Jennifer.Adams@hoganlovells.com
609 Main Street, Suite 4200
Houston, TX 77002

Hannah Leone
Assistant Regional Counsel
U.S. EPA, Region 3
Leone.hannah@epa.gov

Craig Yussen
Environmental Protection Specialist
U.S. EPA, Region 3
Yussen.craig@epa.gov

[Digital Signature and Date]

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 3