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March 31, 2025

Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460
airaction@epa.gov

Re: Subject: Presidential Exemption: Ethylene Oxide Emissions Standards for Sterilization
Facilities: Trinity Sterile, Inc.

Dear Sirs:

On behalf of Trinity Sterile, Inc. (Trinity), we respectfully request a two-year exemption from compliance with the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Commercial Sterilizers (40 CFR Part 63, Subpart O) under Section 112(i)(4) of the Clean Air Act. Information supporting this request is provided below.

Emissions Standards or Limitations Subject to the Request:

- "National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review" (89 FR 24090; April 5, 2024) (Sterilizer Rule)

Facility and Affected Sources:

- Facility Name: Trinity Sterile, Inc.
- Facility Address: 201 Kiley Drive, Salisbury, MD 21801
- Permit Number: 045-0139
- AIRS ID: 1506
- Affected Sources:
 - Sterilization chamber vent
 - Two aeration room vents

Length of Compliance Period Being Requested:

- A two-year exemption, effective as of the compliance date of April 6, 2026, and extending through April 6, 2028.

Justification for the Request:

1. Technology Unavailability:

- The revised NESHAP requires the implementation of a permanent total enclosure (PTE) to capture all fugitive emissions. Most facilities, including Trinity's Salisbury facility, were not initially designed to implement PTE and will require substantial redesign to comply. This redesign process is technologically complex and will vary for each facility; Trinity estimates the process at its facility—including re-

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