UNITED STATMs. Sullivan ENVIRONMENTAL PROTECTION AGENCY
Region 1
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Boston, MA 02109-3912

Clean Air Act Inspection Report

Drafted: January 10, 2023
Finalized: January 19, 2023

EPA Inspector: Davianna Vasconcelos, Environmental Engineer, Air Compliance Section

EPA Reviewer: Darren Fortescue, Manager, Air Compliance Section

Date of Inspection: December 11, 2023

Facility Name: Covidien LP

ICISAir ID#: CT0000000900905468

Facility Location: 195 McDermott Road, North Haven, CT 06473

Mailing Address: 60 Middletown Avenue, Mailstop 7, North Haven, CT 06473

Disclaimer:

Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.

Inspection Attendees:

Name	Title	Organization
Davianna Vasconcelos	Environmental Engineer	EPA R1
Jennifer Shea	Principal Environmental Specialist	Covidien LP
Kevin Sim	Lead Sterilization Technician	Covidien LP
Richard Mather	HVAC Technician	Covidien LP
Ray Potter	Senior Environmental Scientist	CT DEEP
James Conora	Project Manager	Canomara LLC

Facility/Process Description:

Covidien LP ("Covidien"), located at 195 McDermott Road North Haven, CT 06473, was established in 1982. The facility conducts research and development and manufactures and sterilizes surgical equipment. The facility footprint is approximately 1.6 million square feet.

The facility has two production sterilization chambers each with a primary aeration room attached. Both the sterilization chambers and primary aeration rooms are vented to a balancer/oxidizer system. The facility has two secondary aeration rooms that are vented to primary aeration. The facility plans to operate two vacuum degassers, that were installed but not operational at the time of the inspection, as an option for secondary aeration for specific products. The degassers will be vented to balancer/oxidizer system.

The facility has one research and development sterilizer that aerates within the chamber and is vented to the balancer/oxidizer system.

The facility has a balancer/oxidizer ethylene oxide ("EtO") control system manufactured by LENSI. The system was designed to control emissions for up to four sterilization chambers. The balancer uses water in a buffer tank and a stripper column to absorb high concentrations of EtO and equalize the concentration of EtO going to the catalytic oxidizer. The catalytic oxidizer is used to convert EtO into carbon dioxide and water.

Number of Employees and Working Hours:

The facility has approximately 2,900 employees.

The facility operates 24 hours a day, seven days a week.

Potentially Applicable Clean Air Act Requirements:

- 40 CFR Part 63 Subpart O - Ethylene Oxide Emissions Standards for Sterilization Facilities
- Connecticut New Source Review Permit #135-0143
- Connecticut New Source Review Permit #135-0144

Previous Enforcement Actions:

A "Detailed Facility Report" from EPA's Enforcement and Compliance History Online database indicates that there have been no informal or formal enforcement actions taken against Covidien by EPA in the past five years.

EPA's Enforcement and Compliance History Online database indicates that Connecticut Department of Energy and Environmental Protection issued a Notice of Violation to Covidien in December of 2020.

Opening Conference:

EPA representative Davianna Vasconcelos arrived at the facility at 8:00am to meet Jennifer Shea, of Covidien. Ms. Shea led Ms. Vasconcelos to the sterilizer control room where they met Mr. Sim. Ms. Vasconcelos presented her credentials and explained the purpose of visit was to witness the facility's oxidizer efficiency test to meet Subpart O requirement 40 CFR 63.363(b)(4)(i). Ms. Vasconcelos said that a major area of interest was LEL data monitoring during testing and operation as well as the determined EtO residence time through the balancer. Ms. Vasconcelos explained that if any information during the inspection should be considered proprietary, Covidien can submit a Confidential Business Information ("CBI") claim.

Mr. Sim said the control equipment uses two LEL monitors downstream of the balancer. Mr. Sim said the data is recorded and kept for 24 hours at a time. Mr. Sim said the average of the two monitors is set at a maximum of 2.5% and if the maximum is reached, the sterilization system, including the sterilizers, are automatically put into stand-by mode until the LEL returns to levels below 2.5%.

Mr. Mather and Mr. Canora entered the control room. Mr. Mather said Covidien owns a total of 8 LEL monitors that he rotates every 6 months. Mr. Mather said after the LEL monitors are removed from the system, he sends them to a third-party for calibration. Mr. Mather said he cleans the mirrors and emitters on the LEL monitors every two weeks.

Mr. Canora said he is not heating the sample lines or Tedlar bags as there is no concern for condensate in the sample.

Three 1-hour gas samples were collected simultaneously at the catalytic oxidizer inlet and outlet. The samples were collected using Tedlar bags and each sample would be analyzed for EtO on the same day as collection using gas chromatography/flame ionization detector (GC/FID) analysis. EtO mass flow rates were measured at the oxidizer inlet and outlet and destruction efficiency would be demonstrated on a mass basis. Both sterilizers, containing normal product loads, were evacuated during testing to simulate a worst-case challenge to control system.

Facility Testing:

Ms. Shea said each sterilization chamber only conducts one sterilization evacuation process during the entirety of the test meaning the testing runs are completed without recharging the chambers to maximum EtO concentration in between. Ms. Shea said the amount of EtO charged into the sterilizers is not used in the removal efficiency calculation. Ms. Shea said the EtO samples at the oxidizer inlet and outlet are used in the calculation.

Ms. Shea said Covidien completed a project in August 2023 that cascaded emissions from secondary aeration into primary aeration, which is directed straight into the oxidizer, bypassing the balancer.

Ms. Shea said Covidien approximated EtO residence time through the balancer by reading the HFID data that is recorded near the inlet of the oxidizer. Ms. Shea said the HFID continuously records the VOC concentration in ppm going into the oxidizer and by reading the tread, Covidien approximates residence time to be 60 minutes past initial evacuation.

See Attachment 1 for testing run information.

Closing Conference:

Mr. Canora said the gas chromatograph (GC) that would be used to analyze the Tedlar bags was not on site and was approximately 40 minutes away from Covidien at the Canomara office. Mr. Canora said he would run the 6 samples through the GC at the end of the day.

Ms. Vasconcelos requested the following records be sent via email:

- LEL monitoring data from both LEL monitors recorded during testing, and
- HFID monitoring data recorded during testing.

Ms. Vasconcelos left the facility at 11:50am.

Attachment 1: Testing Run Information

Sterilizer Information:

Amount of EtO charged into Sterilizer A: 18.4 lb
Amount of EtO charged into Sterilizer B: 21.8 lb
Total EtO charged: 40.2 lb
Pallet count per sterilizer: 6 pallets

Run 1:

Sterilizer A Evacuation Start Time – 7:30 AM
Sterilizer B Evacuation Start Time – 8:00 AM
Run 1 Sample Start Time – 8:30 AM
Run 1 Sample End Time – 9:30 AM
Ms. Vasconcelos noted no moisture observed in the inlet or outlet samples.
Ms. Vasconcelos witnessed the post-run leak check and noted it was a pass.

Run 2:

Run 2 Sample Start Time – 9:35 AM
Run 2 Sample End Time – 10:35 AM

Run 3:

Run 3 Sample Start Time – 10:40 AM
Run 3 Sample End Time – 11:40 AM
Ms. Vasconcelos noted no moisture observed in the inlet or outlet samples.
Ms. Vasconcelos witnessed the post-run leak check and noted it was a pass.