

1.0 INTRODUCTION AND SUMMARY

1.1 PROGRAM OBJECTIVES

Montrose Air Quality Services, LLC (Montrose) was contracted by Medline Industries, Inc. (Medline) to perform a series of air emission tests at their facility located in Howell, Michigan. The tests were conducted at the inlets and outlets of the dry bed and thermal oxidizer. Testing was performed to determine Destruction Removal Efficiency (DRE) and demonstrate compliance with the source testing limitations of the Michigan Department of Environmental, Great Lakes and Energy (EGLE) Permit No. 24-94B.

The testing was conducted by Alex Webster and Steve Ehresman, of Montrose on October 23, 2019. Jasper Titus of Medline coordinated the testing program. The tests were conducted according to a test protocol 928ET-647141-PP-10, dated September 23, 2019 that was submitted to the Michigan Department of Environmental, Great Lakes and Energy. Montrose performed the tests to measure the following emission parameters:

- Removal efficiency (%) of the dry bed
- Destruction efficiency (%) of the thermal oxidizer

This report presents the test results and supporting data, descriptions of the testing procedures, descriptions of the facility and sampling locations, and a summary of the quality assurance procedures used by Montrose. The average emission test results are summarized and compared to their respective permit limits in Table 1-1 and Table 1-2. Detailed results for individual test runs can be found in Section 5.0. All supporting data can be found in the appendices.

Both qualitative and quantitative factors contribute to field measurement uncertainty and should be taken into consideration when interpreting the results contained within this report. Whenever possible, Montrose personnel reduce the impact of these uncertainty factors by using approved and validated test methods. In addition, Montrose personnel perform routine instrument and equipment calibrations and ensure that the calibration standards, instruments, and equipment used during test events meet, at a minimum, test method specifications as well as the specifications of our Quality Manual and ASTM D 7036-04. The limitations of the various methods, instruments, equipment, and materials utilized during this test have been reasonably considered, but the ultimate impact of the cumulative uncertainty of this project is not fully identified within the results of this report.

**TABLE 1-1
 SUMMARY OF DRY BED REMOVAL EFFICIENCY RESULTS
 HOWELL, MICHIGAN FACILITY
 DRY BED
 OCTOBER 23, 2019**

	Run 1	Run 2	Run 3	Average
Start Time	06:22	07:51	09:14	
Stop Time	07:43	09:06	10:42	
DB Inlet Emissions				
EtO Concentration (ppm)	7.90	14.1	18.2	13.4
EtO Emission Rate (lb/hr)	0.338	0.593	0.721	0.550
DB Outlet Emissions				
EtO Concentration (ppm)	0.0350	0.0810	0.129	0.0817
EtO Emission Rate (lb/hr)	0.00146	0.00340	0.00541	0.00343
EtO REMOVAL EFFICIENCY (%)	99.6	99.4	99.2	99.4

**TABLE 1-2
 SUMMARY OF THERMAL OXIDIZER DESTRUCTION EFFICIENCY RESULTS
 HOWELL, MICHIGAN FACILITY
 THERMAL OXIDIZER
 OCTOBER 23, 2019**

	Run 2	Run 3	Average
Start Time	16:16	18:37	
Stop Time	17:16	19:37	
TO Inlet Emissions			
EtO Concentration (ppm)	88,661	112,866	100,763
EtO Emission Rate (lb/hr)	1,349	2,041	1,695
TO Outlet Emissions			
EtO Concentration (ppm)	0.647	0.445	0.546
EtO Emission Rate (lb/hr)	0.00985	0.00806	0.00896
EtO DESTRUCION EFFICIENCY (%)	>99.9	>99.9	>99.9

1.2 PROJECT CONTACTS

A list of project participants is included below:

Facility Information

Source Location: Medline Industries
Howell, MI facility
301 Catrell Dr
Howell, MI 48843

Project Contact: Jasper Titus
Role: Director of Environmental Health
and Safety

Company: Medline
Telephone: (847)937-2784
Email: jtitus@medline.com

Agency Information

Regulatory Agency: Michigan Department of
Environmental Quality- Air Quality
Division

Agency Contact: Tom Gasloli
Telephone: (517)284-6778
Email: gaslolit@michigan.gov

Testing Company Information

Testing Firm:	Montrose Air Quality Services, LLC (Montrose)	
Contact:	Patrick Clark	Alex Webster
Title:	VP of Emerging Technology	Project Manager
Telephone:	(303)670-0530	(303)670-0530
Email:	pclark@montrose-env.com	awebster@montrose-env.com

2.0 SOURCE LOCATION INFORMATION

2.1 FACILITY DESCRIPTION

Medline Industries operates a three (3) chamber sterilization facility located at 301 Catrell Dr in Howell, Michigan. Products to be sterilized are placed in a sterilization chamber and are exposed to a sterilant gas, ethylene oxide (EtO), at a predetermined temperature, humidity level, and pressure. The EtO penetrates product packaging (e.g., cardboard shipping box, plastic shrink wrap, paper box, and product wrapping) and destroys bacteria and viruses on the product. The product remains sterile until use because bacteria and viruses cannot penetrate the product wrapping.

After the products have been loaded into the chamber the airtight door is sealed. The chamber temperature and relative humidity is adjusted to ensure proper sterilization. The EtO is introduced into the chamber to achieve the desired concentration of EtO. Following sufficient exposure time, an opening is introduced under negative pressure allowing fresh air to enter the chamber and the EtO is evacuated to emission control equipment. This post-cycle vacuum phase typically lasts about 30 minutes.

The high concentrations of EtO are evacuated from the sterilization chamber and vented to control equipment where it is destroyed. All areas of the plant where EtO is present are kept under negative pressure to prevent any fugitive emissions.

Following their removal from the sterilization chamber, the sterile products are placed in an aeration room and kept there for 24 hours. The purpose of aeration is to allow further diffusion of residual EtO from the products prior to shipping in order to comply with the FDA and EPA guidelines for residual EtO. It takes roughly 5 minutes for plant personnel to transfer the sterilized product to the aeration room. EtO concentrations were recorded during this time, but not included in the overall averages used in calculating the destruction efficiency. The aeration room is kept under a constant negative pressure, and fresh air is drawn into the room to “wash” the sterilized product. Nitrogen is injected into the aeration room to further wash the EtO from the product.

2.2 SAMPLING LOCATIONS

Information regarding the sampling locations is presented below:

The dry bed has two inlet ducts. Gaseous emissions sampling occurred at the merge of the two ducts. Flows were taken at both inlet ducts individually to meet Method 1 requirements.

Sample location ID: Dry Bed Inlet 1 (Backflow vent)

Stack exit height: Duct feeds into dry bed

Configuration: Vertical, Circular

Dimensions: 21.75” Diameter

Port locations: Meets Method 1 requirements

Port access: Approximately 15 feet off the ground. Plant supplied lift for flow measurements.

Traverse point information is presented below:

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- Velocity tests -16 points total, 8 from each of two ports located 90° apart from one another.

Sample location ID: Dry Bed Inlet 2 (Aeration room)

Stack exit height: Duct from Aeration room into dry bed

Configuration: Horizontal, Circular

Dimensions: 21.75" Diameter

Port locations: Meets Method 1 requirements

Port access: Approximately 15 feet off the ground. Plant supplied lift for flow measurements.

Traverse point information is presented below:

- Velocity tests -16 points total, 8 from each of two ports located 90° apart from one another.

Sample location ID: Dry Bed Outlet

Stack exit height: 1.5 feet off roof, roof 25 feet off the ground

Configuration: Horizontal, Rectangular

Dimensions: 16.125" x 14.25"

Port locations: Appx. 3' upstream and 4' downstream from any disturbances. Meets Method 1 requirements

Port access: Ladder access to flat roof

Traverse point information is presented below:

- Velocity tests -18 points total, 6 from each of three ports located on top of rectangular duct.

Sample location ID: Thermal Oxidizer

Stack exit height: 30 feet

Configuration: Vertical, Circular

Dimensions: 44 Inches internal diameter

Port locations: Port locations met method 1 requirements of at least 0.5 duct diameters upstream of any disturbances and 2 duct diameters downstream from any disturbance.

Port access: Ladder leads to sampling platform, where permanent guardrails are in place.

Traverse point information is presented below:

- Velocity tests -16 points total, 8 from each of two ports located 90° apart from one another.

3.0 TEST DESCRIPTION

3.1 PROGRAM OBJECTIVES

There were two objectives of this test program. The primary objective was to determine the DRE of control equipment used to limit EtO emission. The inlets and outlets of the dry bed and thermal oxidizer were monitored simultaneously for EtO in determining DRE. EtO was also measured at the outlets to demonstrated compliance with the source testing conditions put forth by the EGLE. The permit limits are presented in Table 3-1.

**TABLE 3-1
EMISSION LIMITS**

Emission Parameter	Units of Measurement	Permit Limits	Emission Limit Reference
Ethylene Oxide	lb/hr	0.044	Permit No. 24-94B
Ethylene Oxide	lb/yr	263	Permit No. 24-94B
Destruction Efficiency	%	99.9	Permit No. 24-94B

3.2 TEST CONDITIONS

Emission tests were performed while the source units, and applicable abatement units, were operating at the conditions required by the permit. Tests were performed at conditions that reflect normal operating procedures. Plant personnel established the test conditions and collected all applicable unit-operating data.

3.3 TEST PROGRAM SCHEDULE

The test program schedule is presented in Table 3-3.

**TABLE 3-3
 TEST MATRIX AND SCHEDULE**

Date	Source ID/ Activity	Sample Runs	Sample Duration
October 23, 2019	Dry Bed		
	EtO Inlet	1, 2, 3	Approximately 60 minutes
	EtO Outlet	1, 2, 3	Approximately 60 minutes
October 23, 2019	Thermal Oxidizer		
	EtO Inlet	2, 3	60 minutes
	EtO Outlet	2, 3	60 minutes

3.4 MONTROSE TEST PROCEDURES

The test procedures used for this test program are summarized in Table 3-4 below. Additional information regarding specific applications or modifications to standard procedures is presented in the following sub-sections.

**TABLE 3-4
TEST PROCEDURES**

Parameter	Measurement Principle	Reference Method
Gas Velocity	Pitot/temperature traverse	EPA 1, 2
O ₂	Paramagnetism	EPA 3A
CO ₂	FTIR	EPA 320
Moisture	FTIR	EPA 320
Ethylene Oxide	FTIR	EPA 320

3.4.1 EPA Method 1 – Traverse Points

EPA Method 1 is used to determine the suitability of each test location and to determine the traverse points used for the gas volumetric flow rate determinations. The test locations must conform to the minimum method requirements of being located at least two duct diameters downstream and at least 0.5 diameters upstream from the nearest flow disturbances, have a cross sectional area greater than 0.785 square feet (ft²).

3.4.2 EPA Method 2 – Gas Velocity

EPA Method 2 is used to determine the gas velocity through each test location using an S-type pitot tube and a Fluke. The gauge is “zeroed” prior to each test run. The sample train is leak checked before and after each run by pressurizing the positive side, or “high” side, of the pitot tube and creating a pressure differential of at least three (3) inches H₂O. The leak check is considered valid if the gauge remains stable for at least fifteen (15) seconds. This procedure is repeated on the negative side by generating a vacuum of at least three (3) inches H₂O. The velocity head pressure (ΔP) and gas temperature (T_s) are then determined at each point specified in EPA Method 1. The static pressure of the stack (P_s) is measured using a water filled U-tube manometer. In addition, the barometric pressure (P_b) is measured and recorded.

3.4.3 EPA Methods 3/3A – Oxygen Concentration

Procedures found in EPA Methods 3 and 3A are used to measure the oxygen (O₂) concentrations in the gas stream. These values are used in the determination of the dry molecular weight of the stack gas. The balance of the stack gas is assumed to be nitrogen (N₂) for this calculation, since the other components in the gas are insignificant for the determination of dry molecular weight. The molecular weight is used, along with the values obtained from the EPA Methods 2 and 320 testing, to calculate the gas volumetric flow rate.

3.4.5 EPA Method 320- Emissions Measurement by FTIR

The EtO concentrations at each test location were determined using EPA Method 320. In Method 320, a sample of the gas stream was continuously withdrawn from the test location and analyzed using a continuous FTIR gas analysis system. This system meets the requirements of EPA methods for gaseous species.

The sample gas was withdrawn from each test location at a constant rate through a stainless-steel probe, a heated glass fiber filter and a heated Teflon sample line. The probe, filter and sample line were operated at a temperature of 200°F or greater to prevent the condensation of moisture. The hot, wet gas was then directed to the FTIR spectrometer gas cell through a heated line. Results from the analyzer were determined on a “wet” volume basis.

The FTIR gas analyzer that was used for monitoring the inlets was an MKS MultiGas FTIR analyzer. A schematic of the sampling system can be found in the Appendix. For the outlets of the dry bed and oxidizer, a MAX Analytical Starboost (optically enhanced) FTIR was used to measure EtO.

A sample spectrum was then recorded in succession. The peak to peak and RMS noise in the resultant spectrum in the wavelength region(s) to be used for the target compound analysis were measured and recorded.

Calibration Transfer Standards (CTS), ethylene and methane, was introduced into the system and two spectra were recorded at least two minutes apart. If the second spectrum was no greater than the first and within the uncertainty of the gas standard, it was used as the CTS spectrum. Otherwise an additional spectrum is created until the spectrum is no greater than the previous spectrum created.

A QA spike was performed by introducing a certified standard of EtO into the sampling system. First, some of the effluent gas was sampled to determine the native concentration of target analytes. The analyte spike calibration gas was then introduced to the FTIR gas cell only, and the results were determined using the analytical algorithm. Results from the calibration gas were recorded and compared to the certified value of the calibration gas. The analyte spike calibration gas was then directed through the entire sampling system and allowed to mix with the effluent gas sample at a known flow rate. The flow ratio of calibration gas to ambient air or source effluent was not greater than 1:10 (one-part calibration gas to ten parts total flow) for the determination of sample recovery. Spectra was recorded for three non-consecutive spiked samples and the concentration of the spike was calculated. The average spiked concentration was within 70% and 130% of the expected concentration. Dynamic spiking was performed for the straight extraction locations, yet due to the percent levels of EtO at the TO inlet, spikes could not be performed. Instead, several calibration gases were measured directly by FTIR, then the same calibration gas was sent through the dilution system. The average of all dilution ratios were used to calculate actual inlet concentrations of EtO.

After all the required pre-test procedures had been performed, stack gas was sampled continuously. Sample interferograms, processed absorbance spectra, background interferograms, CTS sample interferograms, and CTS absorbance spectra were recorded. Sample conditions, instrument settings, and test records were also recorded throughout the test. If signal transmittance changed by five (5) percent or more in any analytical spectral region, a new background spectrum was obtained. A new CTS spectrum was obtained after each sampling run. The post-test CTS spectrum was compared to the pre-test spectrum. For every run the peak absorbance from each spectrum was within five (5) percent of the mean value.

4.0 QUALITY ASSURANCE AND REPORTING

4.1 SAMPLING AND ANALYTICAL QA/QC

Montrose has instituted a rigorous QA/QC program for all of its air pollution testing. Quality assurance audits are performed as part of the test program to ensure that the final results are calculated from the highest quality data. The program ensures that the emission data reported are as accurate as possible. The procedures included in the cited reference methods were followed for all steps of preparation, sampling, calibration, and analysis. Montrose was responsible for preparation, calibration and cleaning of the sampling apparatus. Montrose also conducted the sampling and sample recovery, storage, and shipping.

4.2 QUALITY CONTROL PROCEDURES

Our Quality Assurance Program Summary, located in Appendix D, provides our equipment maintenance and calibration schedule, quality control acceptance limits, and any corrective action that may be needed. For additional quality control, Montrose followed the procedures outlined below and in the method write-ups in Section 3.4.

4.2.1 Equipment Inspection and Maintenance

Each critical piece of field equipment was assigned a unique identification number to allow tracking of its calibration history. All field equipment was visually inspected prior to testing and included pre-test calibration checks

4.2.2 Equipment Calibrations

Our equipment maintenance and calibration schedule is located in Appendix D.

4.3 DATA ANALYSIS, VALIDATION, AND UNCERTAINTY

4.3.1 Equipment Inspection and Maintenance

The raw data collected during the sampling and analysis procedures were used to calculate the results of the testing program. The analysis or reduction of the data to the final results followed these steps, where appropriate to the test method:

- Check field-sampling data for accuracy and calculate appropriate data averages (e.g., temperatures, pressures, volumes, etc.).
 - Double check calculation of the data averages.
 - Review all in-house and contract laboratory reports and ensure that appropriate and/or required QA/QC steps were followed.
 - Enter field to established and verified computer spreadsheets for calculation of volumetric flow rates, mass emission rates or other appropriate results.
 - Double-check all field data inputs.
 - Perform example calculations by hand using raw data on a single test run for each type of emission result reported.
 - Compile summary tables of results and review all table inputs.

This report includes copies of spreadsheet printouts (data input and results output) and example calculation checks. The field data sheets with average data calculations are also included. Standard conditions used for data reduction are 29.92 inches of mercury and 68 °F. All values found to be below the detection limit of the analytical method are reported as “less than” (“<”) either the full detection limit value, one-half of the detection limit, or zero based on the applicable method.

4.3.2 FTIR Data Validation

All FTIR data was submitted to Prism Analytical Technologies (a Montrose company) for reprocessing and validation. The reprocessed data can be found in Appendix A and is reflected in all tables and results. Data validations and other QA/QC including results of calibrations and spikes can be found in Appendix D.2.

5.0 DISCUSSION OF RESULTS

5.1 DETAILED DISCUSSION OF RESULTS

The average results are expressed in Tables 1-1 and 1-2 and more detailed results in Tables 5-2 and 5-3. The test results show that all of the emissions were within their respective permit compliance limits. Emissions have been reported in units consistent with those in the permits.

Additional information is included in the appendices. Appendix D presents the quality assurance information, including instrument calibration data. Raw field data sheets are included in Appendix B. Appendix C presents the general and specific equations used for the emissions calculations and computer spreadsheets.

Because, EtO concentrations at the inlet of the TO are very hazardous, a dilution system was used to transport the sample gas to the analyzer in a safe manner. To transport the sample gas safely, the sampling probe was secured to existing fittings at the oxidizer inlet. Due to the positive pressure and hazardous conditions of the oxidizer inlet, a proper flow traverse could not be conducted while the TO was operating. With the approval from EGLE, the flow was calculated at the outlet of the TO equal to the flow at the inlet.

During the DE testing of the thermal oxidizer, Run 1 was stopped prior to the 1 hour mark due to an equipment malfunction. The strong force of positive pressure of the inlet to the TO broke the glass, critical orifice used to dilute the sample. Due to the nature of the batch process, the orifice was swapped once the sterilization cycle was complete. The TO does not run for approximately 20-30 minutes until the next chamber is ready. During that down time, a new dilution system was installed that prevented orifice damage during the following runs. The results for Run 1 are expressed in the appendices but is not used in calculating the average DE of the TO.

5.2 OUTLET DETECTION LIMIT

The MAX Analytical Starboost FTIR was used in measuring the outlet EtO concentrations. According to ASTM D-6348, the detection limits are calculated as three times the noise equivalent absorbance. The minimum detectable concentration (MDC) for EtO at the outlet was 7.8 ppb. During the DE testing of the TO, several data points were below the detection limit (non-detect). For these data points the detection limit of 7.8 ppb was used in calculating the run average.

**TABLE 5-1
DETECTION LIMIT**

File	Time	EtO Concentration (ppm)
ZERO SYSTEM_0000078.LAB	11:50	0.001
ZERO SYSTEM_0000079.LAB	11:51	0.000
ZERO SYSTEM_0000080.LAB	11:52	0.005
ZERO SYSTEM_0000081.LAB	11:53	0.002
ZERO SYSTEM_0000082.LAB	11:54	0.004
ZERO SYSTEM_0000083.LAB	11:55	0.003
ZERO SYSTEM_0000084.LAB	11:56	0.005
Noise Equivalent Absorbance (Standard Deviation)		0.002
Minimum Detectable Concentration (MDC)		0.0078

**TABLE 5-2
 RESULTS SUMMARY DRY BED ETHYLENE OXIDE EMISSIONS
 MEDLINE – HOWELL, MI
 DRY BED**

<u>Test Parameters</u>	Run 1	Run 2	Run 3	Average
Date	10/23/2019	10/23/2019	10/23/2019	
Start Time	6:22	7:51	9:14	
Stop Time	7:43	9:06	10:42	
<u>Inlet Gas Conditions</u>				
Temperature (°F)	84.0	95.2	94.0	91.1
Volumetric Flow Rate (acfm)	6,720	6,740	6,330	6,590
Volumetric Flow Rate (scfm)	6,240	6,130	5,770	6,050
Volumetric Flow Rate (dscfm)	6,160	6,060	5,700	5,980
<u>Inlet Emissions</u>				
EtO Concentration (ppmwv)	7.90	14.1	18.2	13.4
EtO Emission Rate (lb/hr)	0.338	0.593	0.721	0.550
<u>Outlet Gas Conditions</u>				
Temperature (°F)	92.7	100	94.8	96.0
Volumetric Flow Rate (acfm)	6,590	6,710	6,660	6,650
Volumetric Flow Rate (scfm)	6,090	6,120	6,110	6,100
Volumetric Flow Rate (dscfm)	6,030	6,060	6,050	6,040
<u>Outlet Emissions</u>				
EtO Concentration (ppmwv)	0.0350	0.0810	0.129	0.0817
EtO Emission Rate (lb/hr)	0.00146	0.00340	0.00541	0.00343
EtO REMOVAL EFFICIENCY (%)	99.6	99.4	99.2	99.4

**TABLE 5-3
 RESULTS SUMMARY THERMAL OZIDIZER ETHYLENE OXIDE EMISSIONS
 MEDLINE – HOWELL, MI
 THERMAL OXIDIZER**

<u>Test Parameters</u>	Run 2	Run 3	Average
Date	10/23/2019	10/23/2019	
Start Time	16:16	18:37	
Stop Time	17:16	19:37	
<u>Inlet Emissions¹</u>			
EtO Concentration (ppmwv)	88,661	112,866	100,763
EtO Emission Rate(lb/hr)	1,349	2,041	1,695
<u>Outlet Gas Conditions</u>			
Temperature (°F)	1,387	1,387	1,387
Volumetric Flow Rate (acfm)	8,100	9,620	8,860
Volumetric Flow Rate (scfm)	2,220	2,640	2,430
Volumetric Flow Rate (dscfm)	2,100	2,460	2,280
<u>Outlet Emissions</u>			
EtO Concentration (ppmwv)	0.647	0.445	0.546
EtO Emission Rate (lb/hr)	0.00985	0.00806	0.00896
EtO DESTRUCTION EFFICIENCY (%)	>99.9	>99.9	>99.9

¹ Due to the hazardous conditions at the TO inlet, a flow traverse could not be performed. Flows were taken at the outlet and assumed to be constant.