



STATE OF MICHIGAN

DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

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August 31, 2021

Mary Ann Dolehanty
Division Director, Air Quality Division
Michigan Department of Environment, Great Lakes, and Energy
525 W Allegan St.
Lansing, MI 48933

Dear Ms. Dolehanty:

This letter is in response to your request for a public health evaluation following sampling of ethylene oxide (EtO) in Howell, Michigan, near the Centurion Medical Inc. (Centurion) medical instrument sterilization facility. The Michigan Department of Health and Human Services (MDHHS) evaluated the provided modeled ambient (outdoor) air data and the limited ambient air sample data set and assessed both for short- and long-term public health hazards.

From the available data, **MDHHS concludes that there is insufficient data to determine if there is a long-term public health hazard for increased cancer risk from the measured and modeled EtO levels around the facility and in the nearby community.** This conclusion is based on the levels of EtO in the one round of 24-hour SUMMA[®] canisters that exceed the long-term health comparison values for increased cancer risk. The comparison values represent annual average EtO level, while the available sampling data represent 24-hour average EtO levels. Thus, the currently available ambient air EtO data indicate a possibility for a long-term public health hazard for increased cancer risk, but are not conclusive. Annual average modeling also indicates levels above comparison values for increased cancer risk, but there is no good agreement yet between modeled and measured values.

Additionally, there is no apparent short-term or long-term non-cancer public health hazard. This conclusion is based on all measured and modeled EtO levels being many folds below short-term and long-term non-cancer comparison values.

Given these conclusions, MDHHS recommends that additional EtO ambient air data be collected in the community areas surrounding the Centurion facility to better characterize the annual average level and to verify the air modeling.

Background

The Centurion facility is a medical product sterilization facility located at 301 Catrell Drive in Howell, Michigan. Centurion provides sterilization services to the medical

product industry using EtO. The facility is located in an industrial and residential area on the eastern side of Howell. It is surrounded by neighborhoods to the east and north, and non-residential properties to the south and west (**Figure 1**).

Figure 1. Centurion Medical, Inc. facility located in Howell, Michigan.



Source: Google Earth

Centurion has been using EtO at the site since 1994. The sterilization process used by this facility involves exposing medical equipment to EtO in sealed sterilization chambers followed by a period of aeration in heated, ventilated rooms to allow removal of residual EtO. Emissions are primarily captured by one thermal oxidizer and one dry bed scrubber, but a small amount may also be emitted untreated.

Environmental Data

The resources used for this evaluation can be found on the Michigan EGLE Centurion website located at [Michigan.gov/EGLECenturion](https://www.michigan.gov/EGLECenturion).

Air sampling data

The Air Quality Divisions (AQD) collected seven ambient air samples from six locations near the Centurion facility (EGLE, 2021). This sampling was intended to determine whether EtO was present in the air at detectable levels and if more comprehensive sampling would be necessary. Sample data was also used to help evaluate how well computer-generated models based on stack emissions represented actual EtO concentrations in the immediate vicinity of the Centurion facility. The AQD placed SUMMA[®] canisters at the six sample locations, with two canisters co-located at Site 4 (Appendix A). Samples were collected for 24 hours and then analyzed at the United States Environmental Protection Agency (USEPA) National Contract Laboratory, Eastern Research Group using the USEPA Toxic Organics-15 (TO-15) method. EtO

was detected in all six samples (see **Table 1**), with 24-hour averages ranging from 0.13 to 3.04 $\mu\text{g}/\text{m}^3$ in the immediate vicinity of the facility.

From measurements taken by the USEPA at their monitoring sites in the National Air Toxics Trends Stations and the Urban Air Toxics Monitoring Program networks ([EPA.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-data-summary-national-air-toxics-trends](https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/ethylene-oxide-data-summary-national-air-toxics-trends)), we know there is a national background level of EtO that is not likely to be directly related to facility emissions. This background is not the same throughout the United States and can vary from day to day. EtO is naturally formed in the environment during the breakdown of ethylene by bacteria. It can also be found in tobacco smoke and in the vapor created when gas or diesel fuel are burned (ATSDR, 2020). Because of this day-to-day variance, a local background sample was taken approximately 6 miles south of the facility (Site 6, Appendix A) on the day of sampling. While this sample indicates there is likely a contribution of background to all measurements, values near the facility are above the background concentrations, signifying that background alone does not explain the EtO levels measured.

Table 1. Ambient air sample data collected by AQD on March 29-30, 2021, near the Centurion site.

Ambient air sample	Ethylene oxide (24-h average $\mu\text{g}/\text{m}^3$)
Site 1a	0.13
Site 2	0.70
Site 3	3.04
Site 4a	0.31
Site 4b	0.35
Site 5	2.29
Site 6 (background)	0.07

Air modeling data

The AQD modeled 24-hour and annual average ambient EtO concentrations from the Centurion stack emissions to evaluate the potential impact of site emissions (EGLE, 2021). Results from the annual average model, are shown in **Figure 2**. Measured 24-hour average were also modeled and compared to the 24-hour measured SUMMA[®] canisters averages.

The EGLE modeling report stated: “The summa concentrations, minus the background concentration of 0.0712 $\mu\text{g}/\text{m}^3$, ranged approximately 60 to 6,000 times higher than the modeling results. The background concentration was subtracted to approximate “company only” impacts to the summa cannisters” “This indicates additional sources of

Figure 2. Modeled annual average EtO concentrations in ambient air shown in $\mu\text{g}/\text{m}^3$. Source: EGLE (2021)



EtO are not accounted for in the model.” Therefore, all modeling results will need to be confirmed with further sampling events.

Potential Health Concern

EtO is the chemical of concern associated with the Centurion facility and is the only chemical that was modeled and measured around this facility. EtO is readily absorbed through inhalation and is easily distributed throughout the human body. EtO leaves the body rapidly within approximately two to three days after exposure (ATSDR, 1990). EtO is a human carcinogen which acts via a mutagenic mode of action. Acute exposure to high EtO levels can cause non-cancer health effects such as lung irritation, headaches, and memory loss, numbness, nausea, and vomiting. Chronic exposure to lower levels may also cause non-cancer health effects (CalEPA, 2008).

Comparison values

In December 2016, USEPA released an updated evaluation of the carcinogenicity of EtO. The evaluation included derivation of an updated inhalation unit risk estimate over a 70-year lifetime (USEPA, 2016). This value is the basis for the ATSDR Cancer Risk Evaluation Guide (CREG) and EGLE’s Initial Risk Screening Level (IRSL) (**Table 2**). The California Environmental Protection Agency (CalEPA) developed a chronic Reference Exposure Level (REL) based on rat studies showing neurological effects such as impaired movement and reduced reflex response (CalEPA, 2008).

Table 2. Comparison values used to evaluate acute and chronic inhalation exposure to EtO near the Centurion facility.

Health Effects	Exposure Duration	Comparison Values
Cancer	Chronic/Long-term exposure	EGLE IRSL ² (0.0002 µg/m ³), ATSDR CREG ³ (0.00021 µg/m ³)
Non-cancer	Short-term exposure	ATSDR Intermediate EMEG ⁴ (160 µg/m ³)
	Chronic/Long-term exposure	CalEPA REL ⁵ (30 µg/m ³)

²Initial Risk Screening Level (MDEQ, 2017)

³Cancer Risk Evaluation Guide (ATSDR, 2019)

⁴Environmental Media Evaluation Guide (ATSDR, 2019)

⁵Reference Exposure Level (CalEPA, 2008)

With a maximum 24-hour average measured EtO concentration of 3.04 µg/m³ in the six samples while Centurion was operating, it is highly unlikely that short-term or long-term average EtO levels are high enough to pose a non-cancer health hazard in the community. This value is well below both the CalEPA REL of 30 µg/m³ and ATSDR Intermediate EMEG of 160 µg/m³.

For comparison to the chronic cancer-based comparison values, all six 24-hour SUMMA[®] canister samples and the modeled annual average concentrations exceed the IRSL and CREG of 0.0002 µg/m³, which both have a theoretical cancer risk of 1 extra case of cancer in 1 million people similarly exposed. Also, in some of the annual average modeled concentrations and all measured 24-hour samples, including the measured background sample, the EtO levels are greater than a 0.02 µg/m³ comparison

value. $0.02 \mu\text{g}/\text{m}^3$ is the EtO level with a theoretical cancer risk of 1 extra case in 10,000 people similarly exposed (**Table 1 and Figure 2**). The exceedance of the cancer-based comparison values does indicate the potential for a public health concern; however, given measured EtO levels for only one 24-hour period, along with the poor agreement between 24-hour modeled (EGLE, 2021 table 3) and measured results, more sampling is needed to fully evaluate the long-term hazard.

Conclusions

The MDHHS concludes that there is insufficient data to determine if there is a long-term public health hazard for increased cancer risk from the measured and modeled EtO levels around the facility and in the nearby community. This conclusion is based on the levels of EtO in the one round of 24-hour SUMMA[®] canisters that exceed the long-term health comparison values for increased cancer risk. The comparison values represent annual average EtO level, while the available sampling data represent 24-hour average EtO levels. Thus, the currently available ambient air EtO data indicate a possibility for a long-term public health hazard for increased cancer risk but are not conclusive. Annual average modeling also indicates levels above comparison values for increased cancer risk, but there is no good agreement yet between modeled and measured values.

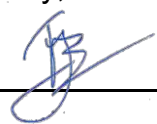
Additionally, there is no apparent short-term or long-term non-cancer public health hazard. This conclusion is based on all measured and modeled EtO levels being many folds below short-term and long-term non-cancer comparison values.

Recommendations

MDHHS recommends that additional EtO ambient air data be collected in the community areas surrounding the Centurion facility in order to better characterize the annual average level and to verify the air modeling.

These conclusions and recommendations may be updated as additional information becomes available. If you have any questions or concerns, please contact MDHHS - Toxicology and Assessment Section at 1-800-648-6942. You can also contact me directly at (517) 284-0244 or by email at VanterveJ@Michigan.gov.

Sincerely,



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Centurion Medical Products Corp. (N5109) Supplement Modeling Summary

https://www.michigan.gov/documents/egle/2021-04-23-Centurion-Modeling-Report_723159_7.pdf

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Appendix A

Sample locations from March 29-30, 2021 sampling event



Figure 8 Centurion Medical Products Sampling Sites for Phase I

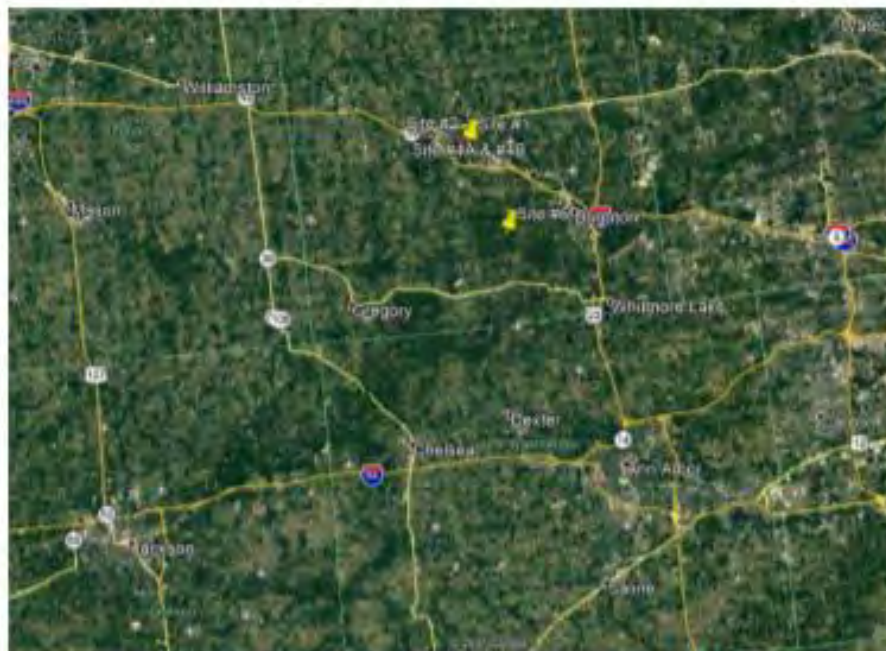


Figure 9 Background and Centurion Medical Products Sites for Phase I sampling.

https://www.michigan.gov/documents/egle/2021-04-21-Centurion-Medical-Products-Sampling-Report_723149_7.pdf