

FAQ

Ethylene Oxide Air Emissions Viant Medical Inc.

520 Watson Street SW, Grand Rapids, Michigan

Frequently Asked Questions (FAQ)

These frequently asked questions have been compiled to answer the community’s questions about ethylene oxide emissions in a general sense, as well as specific questions related to the Viant Medical Inc. (Viant) facility.

Contents

- General Information** 2
 - 1. What is ethylene oxide and what are its uses? 2
 - 2. Is ethylene oxide naturally occurring? 2
 - 3. Is ethylene oxide dangerous? 2
- Health Information** 2
 - 4. How does the Michigan Department of Environment, Great lakes and Energy (EGLE) regulate ethylene oxide in air emissions? 2
 - 5. Can exposure to ethylene oxide cause immediate or acute health effects? 2
 - 6. Can ethylene oxide cause cancer? 2
 - 7. How long does ethylene oxide stay in my body? 2
 - 8. Is there a way to test my ethylene oxide exposure? 2
- Viant and Ethylene Oxide Concerns** 3
 - 9. Does Viant have a permit for their ethylene oxide emissions? 3
 - 10. Is Viant operating within their permitted limits? 3
 - 11. What actions is EGLE requiring Viant to take? 3
 - 12. What levels of ethylene oxide are in the air near Viant? 3
 - 13. Are the levels of ethylene oxide near Viant high enough to cause noncancer health effects? 3
 - 14. Are cancer rates high in this area? 3
 - 15. What is my risk of cancer from living in this area? 4
 - 16. What is EGLE doing to better understand and reduce ethylene oxide emissions from Viant? 4
 - 17. What is the USEPA doing to better understand and reduce ethylene oxide across the country? 4
- Air Monitoring** 4
 - 18. Where have the outdoor air samples been taken? 4
 - 19. Will the results of the sampling be shared with the public? 4
- Enforcement Actions** 4
 - 20. What is a Consent Order? 4
 - 21. What does the proposed Consent Order require Viant to do? 4

General Information

1. What is ethylene oxide and what are its uses?

Ethylene oxide is a gas with many industrial uses. There are two key uses for ethylene oxide: 1) It is used to make other chemicals that produce many everyday products and 2) It is used to sterilize devices that can't be sterilized using steam, such as some medical and dental equipment. This is how Viant uses ethylene oxide at their facility.

2. Is ethylene oxide naturally occurring?

Yes. In addition to its industrial uses, ethylene oxide also occurs naturally in our bodies from metabolizing food. We all have some ethylene oxide in our bodies. Exposures to ethylene oxide in the air we breathe can add to our natural levels.

3. Is ethylene oxide dangerous?

Yes. In the workplace, ethylene oxide needs to be managed so that it does not pose a fire or explosion risk, and to limit exposures to workers. As an outdoor air pollutant, it is designated by the U.S. Environmental Protection Agency (USEPA) as one of the 187 Hazardous Air Pollutants. At high enough levels of exposure, it can pose a cancer risk.

Health Information

4. How does the Michigan Department of Environment, Great Lakes and Energy (EGLE) regulate ethylene oxide in air emissions?

Since 1982, EGLE has regulated ethylene oxide in air emissions as a **probable** human carcinogen based on animal studies. In December 2016, the USEPA classified ethylene oxide as a **known** human carcinogen based on studies of workers. In order to help ensure that public health is protected, EGLE restricts air emissions of ethylene oxide and other air pollutants when it issues air permits to companies

5. Can exposure to ethylene oxide cause immediate or acute health effects?

At very high levels in the air, ethylene oxide can cause immediate health effects, like headaches, dizziness, nausea, fatigue, and respiratory irritation. Based on the levels observed around Viant, immediate health effects are unlikely to occur.

6. Can ethylene oxide cause cancer?

Yes. At certain exposure levels, ethylene oxide can cause lymphoid cancers (including multiple myeloma, leukemia, Hodgkin lymphoma, and non-Hodgkin lymphoma) and breast cancer in females.

7. How long does ethylene oxide stay in my body?

Ethylene oxide is removed from the body quickly. Almost 90 percent of ethylene oxide would be eliminated from the body in two hours.

8. Is there a way to test my ethylene oxide exposure?

While there are tests to estimate current contact with ethylene oxide, they would be accurate only for a very recent and high exposure. These tests would not be helpful in telling you about your risk for future health problems.

Viant and Ethylene Oxide Concerns

9. Does Viant have a permit for their ethylene oxide emissions?

Yes. Viant's most recent [air permit](#) was issued in 2005. This permit requires the operation of air pollution control equipment to remove ethylene oxide before emissions are exhausted to the atmosphere.

NOTE: Air permits are issued prior to installation of the equipment and are good for the life of the equipment. Permits must be re-evaluated when certain changes are proposed for that equipment or if a company wished to install new equipment. Viant has not made changes to their equipment or proposed to install new equipment at this time.

10. Is Viant operating within their permitted limits?

In July 2018, EGLE Air Quality Division cited Viant in [violation](#) of the permitted emission limit and received a [response from Viant](#). Since then, stack testing has been conducted and the results indicate emissions from the stack at Viant are below permitted limits.

11. What actions is EGLE requiring Viant to take?

EGLE is requiring that Viant conduct their own outdoor air sampling for ethylene oxide as well as other measures included in the Consent Order as detailed below. The air sampling is being conducted monthly.

Several violation notices have been issued to the company, which has led to EGLE entering into an [enforcement action](#) with Viant. This enforcement action is in the form of a legal document called a Consent Order.

12. What levels of ethylene oxide are in the air near Viant?

In October 2018, EGLE Air Quality Division conducted a [modeling study](#), which looked at the emissions using a computer model. As a result of this modeling study, we estimate that the nearest and most impacted residential area has an average level of 0.3 micrograms per cubic meter of ethylene oxide in the outdoor air. For perspective, the USEPA has estimated that the average ethylene oxide level in the US is 0.0062 micrograms per cubic meter in outdoor air.

13. Are the levels of ethylene oxide near Viant high enough to cause noncancer health effects?

No. The ethylene oxide levels do not pose a concern for short-term or long-term noncancer health effects, based on the Viant emission estimates, EGLE modeling and air sampling done in the community. EGLE started an air monitoring study in November 2018 and again in March 2019 to help evaluate the level of actual emissions.

14. Are cancer rates high in this area?

MDHHS reviewed the number of cancer diagnoses in the area and found:

- There were slightly fewer breast cancer cases in the area than we would expect to see when compared to both Kent County and the State of Michigan.
- There were slightly more multiple myeloma cases in the area compared to Kent County, but when compared to the State of Michigan, there was no significant difference in the number of cases.
- There was no significant difference in the number of cases of leukemia, Hodgkin lymphoma, or non-Hodgkin lymphoma in the area compared to either Kent County or the State of Michigan.

It is important to note that the cancer data used for this review does not have the information needed to link cancer diagnoses with any chemicals, including ethylene oxide. The full report is available at [Michigan.gov/documents/mdhhs/Viant_Cancer_Incidence_Review_661354_7.pdf](https://michigan.gov/documents/mdhhs/Viant_Cancer_Incidence_Review_661354_7.pdf)

15. What is my risk of cancer from living in this area?

The overall risk of getting cancer in your lifetime living anywhere in the United States is 40%, which can also be expressed as 400,000 in one million. EGLE has estimated the additional increased risk of getting cancer from long-term exposure to ethylene oxide from Viant is 0.15% or 1500 in one million. This estimate is for the nearest residential area near Viant. More distant residential areas have lower ethylene oxide levels and risks.

It is important to note that cancer risk describes the chance or potential of developing cancer. It does not mean that someone will definitely develop cancer.

16. What is EGLE doing to better understand and reduce ethylene oxide emissions from Viant?

EGLE conducted outdoor air monitoring in November 2018 and again in March 2019 and a stack test of emissions was done by Viant in December 2018. Additionally, part of their compliance plan, Viant is taking monthly ethylene oxide samples on their property boundaries. EGLE is participating, by collecting their own samples and reviewing results from Viant's samples to ensure emissions are as expected. Emissions of ethylene oxide will be eliminated following the shutdown of the sterilization system at the end of 2019.

17. What is the USEPA doing to better understand and reduce ethylene oxide across the country?

The USEPA is reviewing the Clean Air Act regulations for facilities that emit ethylene oxide to determine if emissions standards should be tightened. USEPA is also conducting air sampling in several locations across the county. Information on USEPA action can be found at www.epa.gov/hazardous-air-pollutants-ethylene-oxide.

Air Monitoring

18. Where have the outdoor air samples been taken?

EGLE has conducted two phases of ethylene oxide air sampling around Viant. Phase I Sampling was limited and took place primarily on the Viant property and Phase II took place in the community near the Viant property. Maps for both sampling locations can be found at www.michigan.gov/viant.

19. Will the results of the sampling be shared with the public?

The sampling results for both sampling events can be found at www.michigan.gov/viant, under "What is EGLE doing?" Additionally, any sampling results from Viant will be posted as they are received.

Enforcement Actions

20. What is a Consent Order?

A Consent Order is a legally enforceable voluntary settlement that contains a compliance program to resolve alleged air quality violations to ensure they are not repeated, as well as a monetary penalty.

21. What does the proposed Consent Order require Viant to do?

The proposed Consent Order requires Viant to make operational changes in the handling of sterilized equipment, comply with the requirements in their air permit, conduct sampling for ethylene oxide around the facility on a monthly basis and cease sterilization activities at the facility by December 31, 2019. Any use of ethylene oxide beyond that date as required by the Food and Drug Administration will cease by January 31, 2020. Viant will also pay a \$110,000 penalty. Additionally, the Consent Order includes specific penalties the company must pay if it does not meet these commitments.

Michigan's Environmental Justice Policy promotes the fair, non-discriminatory treatment and meaningful involvement of Michigan's residents regarding the development, implementation, and enforcement of environmental laws, regulations, and policies by this state. Fair, non-discriminatory treatment intends that no group of people, including racial, ethnic, or low-income populations, will bear a disproportionately greater burden resulting from environmental laws, regulations, policies, and decision-making.

Meaningful involvement of residents ensures an appropriate opportunity to participate in decisions about a proposed activity that will affect their environment and/or health.