

Proposal for Phase II Ambient Air Sampling Ethylene Oxide at Viant Medical, Grand Rapids

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Introduction

This plan describes the ambient air sampling activities that the Michigan Department of Environmental Quality intends to carry out adjacent to and in the neighborhoods near Viant Medical, Inc. (Viant) in Grand Rapids, Michigan.

Section 1: Project Description

1.1 Overview

Viant has been identified by EPA NATA (Environmental Protection Agency National Air Toxics Assessment) results as having elevated Ethylene oxide ambient air impacts. These impacts are above Michigan's Initial Risk Screening Level (IRSL) ($0.0002 \mu\text{g}/\text{m}^3$) and Secondary Risk Screening Level (SRSL) ($0.002 \mu\text{g}/\text{m}^3$) for Ethylene oxide. Monitoring for Ethylene oxide can be accomplished using the TO-15 SUMMA canister method. EPA's National Contract Laboratory, Eastern Research Group (ERG), can perform the analysis for \$162.00/sample. The laboratory detection limit is $0.0819 \mu\text{g}/\text{m}^3$. MDEQ's SRSL for ethylene oxide is $0.002 \mu\text{g}/\text{m}^3$. Since the SRSL is lower than the detection limit of the current method for ethylene oxide, the monitoring data will have to be carefully interpreted. If a sample result is reported non-detect, the actual level could still be above the SRSL.

1.2 Project Objective

The objective of the ambient air sampling activities is to reliably detect and quantify ambient air ethylene oxide concentrations near Viant with EPA Method TO-15 via 24-hr samples. This phase of the study will be done on three separate days. After each of the sampling days, the data will be analyzed to determine the impacts from the facility. This will allow the MDEQ to obtain a baseline of community impacts at the current emission level. Then as the company makes improvements, two additional rounds of testing may be done to see how the changes affect the levels of ethylene oxide detected. This would provide a basis for additional actions by the MDEQ including, but not limited to, additional monitoring, ethylene oxide exposure assessment, and enforcement activities.

Section 2: Project Monitoring Design

2.1 Site Selection

Phase II sampling design is built off the results of Phase I sampling and will determine the extent of ambient air impacts of ethylene oxide in the community around Viant. This phase would involve three (3) days of field sampling, deploying 20 canisters per day, at approximately 18 different locations, in the area surrounding the facility. The study area of Phase II is shaded

purple in Figure 1. The locations for the sampling will take into consideration the wind direction on day of sampling. The exact locations for sampling will not be determined until the day of sampling, however priority will be given to sampling locations in residential areas. The study area will be within the area with a modeled maximum 24-hour concentration over a year (based on 2018 actual emissions) that is greater than the method detection limit (MDL) of $0.0819 \mu\text{g}/\text{m}^3$. The National Weather Service data and the MDEQ Monroe Street Air Monitoring Station's meteorological data will be used to determine the expected wind direction for the sampling data and the direction at the time of canister placement. The Monroe Street Air Monitoring Station is approximately 1.7 miles northeast of the Viant Facility.

Ahead of the field study, permissions to sample on Grand Valley State University property and the City of Grand Rapids property will be obtained. The Kent County Health Department will also be consulted on sampling at individual residences.

Sampling will take place upwind of the facility, at the location of highest concentration area from Phase I, the ambient air site from Phase I, and at a concentration gradient going away from the facility. Canister placement: place canisters at 2 different upwind sites and co-locate at one of these sites; place the remaining canisters in the downwind direction, co-locating at approximately 10% of the overall number of sites. In addition to upwind sites, consideration will also be given to trying to obtain a 'background' level of ethylene oxide for the general area.

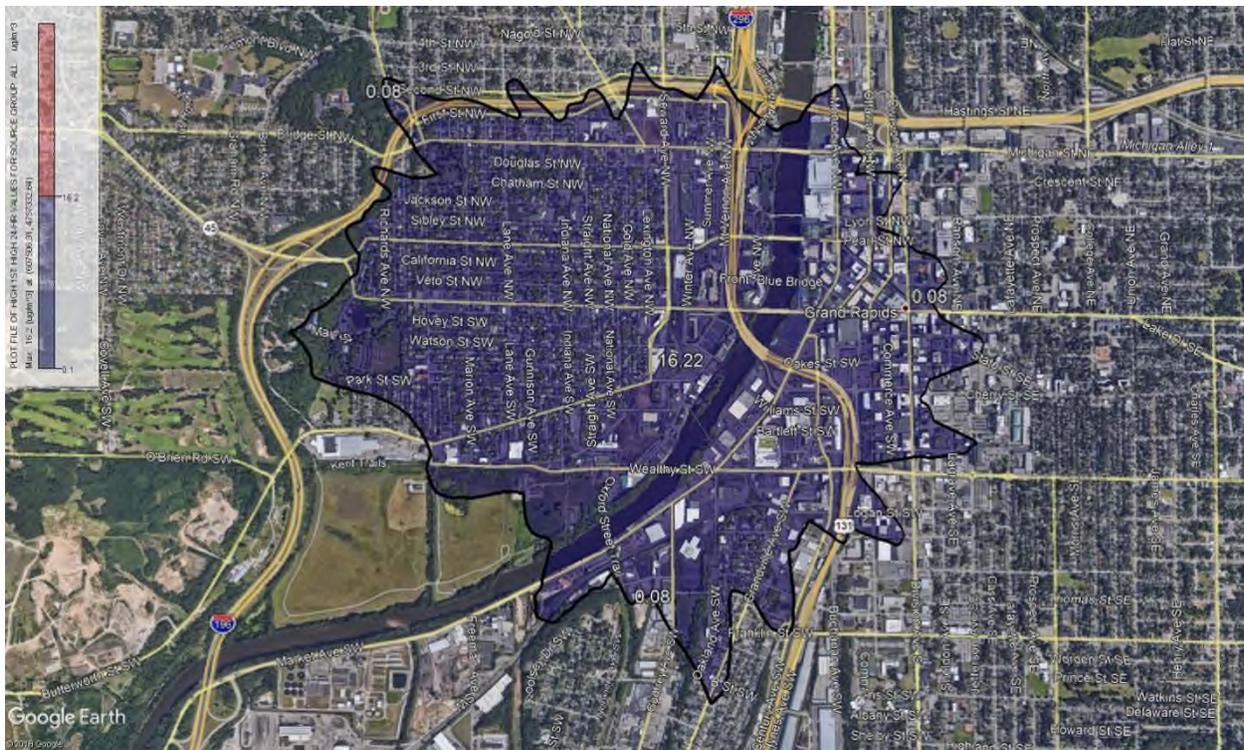


Figure 1: Phase II Study Area 24-hour Modeling Isopleth shows MDL ($0.0819 \mu\text{g}/\text{m}^3$)

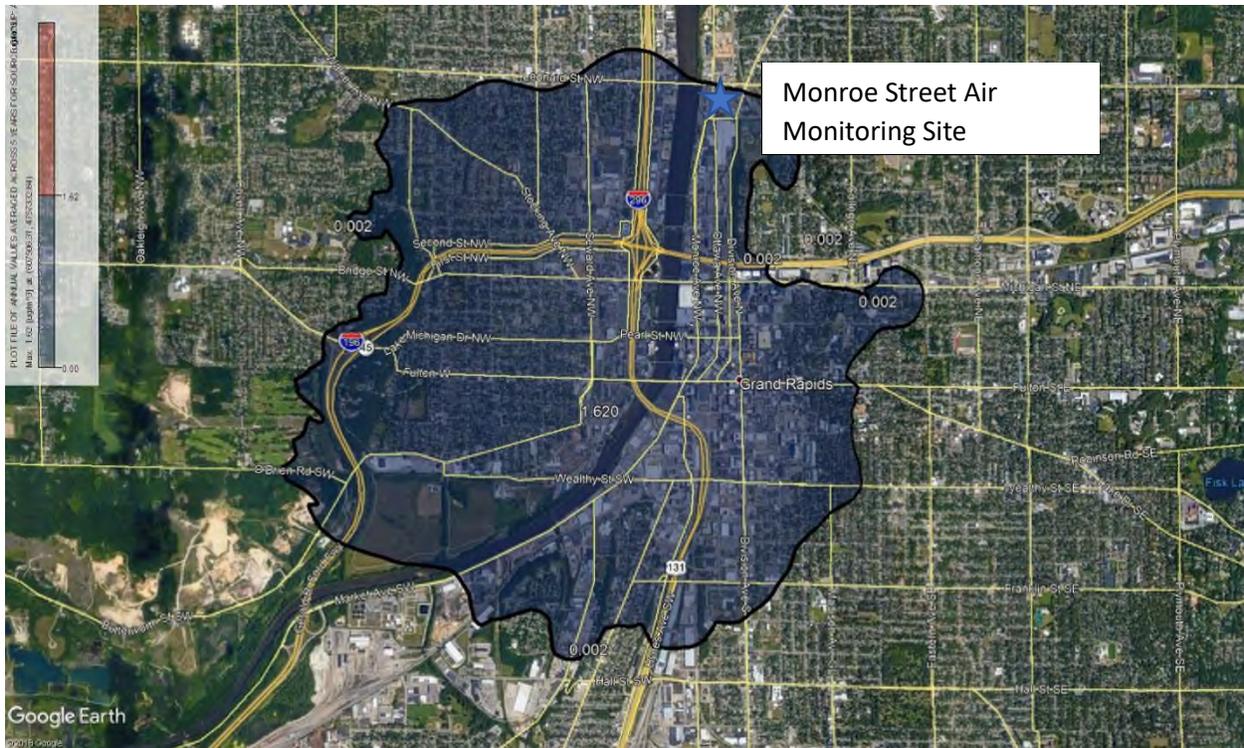


Figure 2: Modeling Isopleth for SRSL (0.002 µg/m³)

2.2 Monitoring Siting

The MDEQ will follow the monitor siting criteria detailed in the Code of Federal Regulations (CFR) Chapter 40 Section 58, Appendix E, where relevant and appropriate for this monitoring program. MDEQ will consider canister placement guidelines such as the following:

- Locating the canister in an area that has an unobstructed air flow, especially in the direction of any recognized sources of target analytes (following MDEQs Sampling Plan for this study and any specific instructions from ERG that accompany the canisters);
- Avoiding locations that are directly influenced by nearby adjacent, biasing emission sources to the extent possible;
- Avoiding locations where reactive surfaces may cause chemical changes in the air sampled;
- Documenting the canister siting location with information such as digital pictures of the site from the eight cardinal directions, sampler height and GPS coordinates (Using the Sampling Location Identification Form for this study).

2.3 Meteorological Measurements

The MDEQ will utilize the meteorological measurements that are made at the Grand Rapids – Monroe Street Site. This site is approximately 1.7 miles northeast of Viant and within the modeling isopleth of the SRSL, see Figure 2. Meteorological measurements made at sites in the

MDEQ monitoring network are sited, audited and certified annually as required by the Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements Version 2.0.

2.4 Measured Pollutant

The site-specific pollutant that the MDEQ will monitor is ethylene oxide (IUPAC name; oxirane, CAS # 75-21-8). ERG will perform the sample analysis for this study.

Section 3: Monitoring Protocols

3.1 Sampling Frequency, Duration and Quantity

MDEQ will conduct ambient air sampling on three days at approximately 18 monitoring sites each sampling day. Sampling days will be coordinated with ERG. The sites will be selected on the sampling day, due to variation in wind directions. The sites will be a mixture of upwind, downwind, and background sites. A majority of the sites will be downwind. At least, one downwind site will have a co-located canister. The second co-located site will be picked at random on the day of sampling. The sites will be chosen based on the modeling results from the detection limit isopleth (see Figure 1) and the prevailing wind direction on the day of sampling.

3.2 Field Sampling Methods.

Consistency of measurement is necessary to achieve the program objectives described above. The ability to accurately detect pollutant concentrations and evaluate the data to assess the degree to which associated health risks may be present requires a considerable level of standardization. To achieve these objectives, these ambient air sampling activities will follow EPA Method TO-15 for the sample collection and the MDEQ SOP 8.17 "VOC Fixed Orifice Sampling" Version 0.0 Dated 10/2/2018.

The sampling apparatus will consist of SUMMA or fused silica-lined, 6-liter canisters and critical orifice passive sampling kits that are calibrated for 24-hour samples without the use of electricity. Field sampling staff will place the canisters in the field and manually start and stop the sample collection. Inlet height will be approximately 2 meters. The sampler should remain under vacuum (negative pressure) after sample collection, and during delivery to ERG.

Field sampling staff will collect two co-located samples per sampling event. The co-located samples will require a separate sample inlet for each canister at the co-located site. The field sampling staff will select the co-located sampling locations based on prevailing wind direction the day of sampling, such that it is downwind of the facility. Should the wind be light and variable, the field sampling staff will select the co-located sampling location from the locations that are historically downwind from the facility. Samples will be logged on a chain of custody form provided by ERG, and the form and samples will be sent to ERG within 24 hours of sampling.

3.3 Sample Analysis Methods

Like the field sample collection, the analysis of the samples collected for these ambient air monitoring activities will follow EPA Method TO-15.

The analytical laboratory will use sample pre-concentration and Gas Chromatograph (GC)/Mass Selective Detector analysis in Selected-ion Monitoring/Scan mode; will perform GC/Vass Spectrometer calibration curves of ethylene oxide; and will use daily Continuing Calibration Verification checks to ensure proper QA/Quality Control (QC) of sample analyses. For instance, the analytical laboratory will use the co-located sample to check method precision.

The analytical laboratory determined the minimum detection limits that will be used to ensure that detection goals are met. The Minimum Detection Limit (MDL) established for ethylene oxide by ERG is 0.0453 parts per billion volume (ppbv) or 0.0819 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$).

Along with the analysis of the canister, to facilitate the field sampling, ERG is responsible for cleaning of the canisters and sampling apparatus and preparing and delivering them to MDEQ. ERG will also be responsible for calibrating and verifying the correct operation of the flow controllers to ensure the validity of the 24-hour samples.

Once the sample analysis is validated, ERG will send the data report and data summary to MDEQ.

Section 4: Data Reporting Requirements

4.1 Sample Data

Quality assured ambient monitoring data will be reported by ERG to MDEQ in ppbv and $\mu\text{g}/\text{m}^3$. ERG will report the date for the sample as the end date of the collection of that sample.

All data, including values below the MDL, will be reported to the MDEQ. Data should not be substituted (e.g., $\frac{1}{2}$ MDL.) If necessary, ERG will report data with the units of ppb and will use the National Air Toxics Trend Station Technical Assistance Document (Data Management Section) flags. For instance, the data tables will include these QA data flags for data below the MDL and null data.

4.2 Meteorological Data

Meteorological data will be collected and summarized in 5 minute and 1-hour intervals at the Grand Rapids Monroe Street site.

Section 5: Quality Assurance Project Plan

All environmental data operations associated with MDEQs air toxics monitoring program must fully comply with EPA Publication QA/G5: "Guidance for Quality Assurance Project Plans" (http://www.epa.gov/quality/qa_docs.html). Thus, this monitoring program will follow the Quality Assurance Project Plan (QAPP) developed by MDEQ, in accordance with the guidance document. The QAPP is "Viant Ethylene oxide Monitoring Grand Rapids, MI" Version 0.0 October 31, 2018.

Section 6: Role and Responsibility

MDEQ is responsible for

- Determining sample locations
- Site setup and monitoring
- Gathering access information for sampling locations
- Establishing and operating the monitoring site(s) and using the sampling and analysis methodology described in this plan
- Complying, with all other standards and protocols described in this plan, including the timely handling of incoming and outgoing sample media
- Coordinating field sampling activities
- Coordinating with ERG to provide and analyze the canisters during the sampling period.
- Sharing data with Michigan Department of Health and Human Services, Kent County Health Department, City of Grand Rapids, Michigan Occupational Safety and Health Administration, and Grand Valley State University.

Once the data results are received from the laboratory, Air Monitoring Unit staff will consult with Toxics Unit and Grand Rapids District staff. The results from each sampling day will be analyzed independently and a memo or report will be generated to document the investigation and findings. This report will be available 2-3 weeks after sampling results are received from the laboratory. This will be publicly shared on the MDEQ website at www.michigan.gov/viant.