January 25, 2019

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RE: Violation Notice from Michigan Department of Environmental Quality to Viant Medical, Inc. on January 4, 2019

Dear Ms. Lazzaro:

Viant Medical, Inc. (Viant) appreciates the opportunity to submit this response to the Michigan Department of Environmental Quality's (MDEQ's) Violation Notice dated January 4, 2019.

As you know, the use of ethylene oxide (EtO) is critical to ensuring the safety of patients and physicians through the sterilization of specific and complex medical devices. Devices that need to be sterilized by EtO include complex items such as pace makers and implantable defibrillators. The industry's use of EtO as a sterilant accounts for less than 1 percent of EtO use globally.

In this response, we highlight a number of steps Viant has taken, and will take, to address fugitive EtO emissions. Viant is committed to continuing to work with MDEQ to further reduce EtO emissions from the facility.

Viant understands MDEQ's concerns related to the health effects of EtO emissions, and takes those concerns seriously. But Viant also believes that MDEQ's use of Rule 901(a) to allege a violation based on a revised ambient-air standard applicable only to new or modified facilities is not consistent with the language or intent of the regulation.

Additionally, we would note the following:

1. In July 2017, Viant self-reported a facility malfunction that resulted in excess fugitive emissions of EtO. Since that time, Viant has maintained regular communications with MDEQ, and has taken corrective actions and voluntary remedial measures, including the elimination of the specific process that produced a majority of the facility's fugitive EtO emissions.

2. The MDEQ's 24-hour sampling survey conducted on November 29 and 30 does not accurately estimate Viant's potential impact on ambient EtO levels. As described in more detail below, relying on a single instance of sampling conducted outside the Viant facility is inconsistent with the methodology currently being used by the Environmental

Protection Agency (EPA) in similar ongoing surveys. MDEQ's survey results also do not appear to account for existing background levels of EtO or the potential presence of vehicle exhaust from nearby highways and adjacent vehicle traffic as well as cigarette or tobacco smoke at the sample sites, which are potential sources of ambient EtO. Due to this, more rigorous and prolonged testing is needed to ensure a clear understanding of the impact of potential fugitive emissions from the Viant facility.

We look forward to working with you and to having an opportunity to discuss these matters with you in greater detail.

I. Background

In July 2017, Viant became aware of a malfunction in one of its sterilization chambers that resulted in excess fugitive emissions of EtO and caused the Viant sterilization facility to exceed the twelve-month rolling emission limit for EtO established in its Permit to Install (PTI No. 605-89B). In accordance with Michigan Air Pollution Control Rule 912, Viant (then operating as MedPlast Sterilization Services) self-reported the July 2017 emission event to MDEQ.

Viant took immediate corrective action to remedy the malfunction that caused the July 2017 permit exceedance. Following the July 2017 emission event, Viant also engaged in a voluntary review of its sterilization processes to identify additional actions that could be taken to reduce fugitive emissions from the Viant facility. As MDEQ is aware, Viant has since taken additional, voluntary steps to reduce fugitive emissions from the sterilization facility including the elimination of the specific sterilization cycle that produced the majority of the facility's fugitive EtO emissions. Per EPA's November 21, 2018 inspection report and recommendations, Viant also intends to implement operational changes so that sterilized equipment remains in the sterilization chamber for a longer period of time, permitting additional EtO emissions to be vented to the scrubbers, while the sterilized equipment awaits transfer to the aeration cells. Viant has engaged outside consultants to further evaluate the feasibility of routing fugitive emissions from the facility to a stack to facilitate dispersion, and to investigate potential control options for fugitives. Viant is committed to continuing to work cooperatively with MDEQ to identify additional, feasible steps to reduce EtO emissions from the Viant sterilization facility.

II. MDEQ's January 4 Notice of Violation

In the January 4 Violation Notice, MDEQ alleges the Viant Facility violated Rule 901(a) based on elevated concentrations of EtO. MDEQ relies on the results of canister sampling conducted by MDEQ on November 29 and 30, 2018, as the basis for the alleged violation. According to MDEQ, the sampling results indicated EtO levels above the current Initial Risk Screening Level (IRSL) and Secondary Risk Screening Level (SRSL) for EtO and thus constitute a violation of Rule 901(a). For the following reasons, Viant believes that MDEQ's reliance on the November canister-sampling results is misplaced, and objects to the use of the IRSL/SRSL as the basis for an alleged 901(a) violation.

A. Rule 901(a)'s Regulatory Language

Under Air Pollution Control Rule 901(a), "a person shall not cause or permit the emission of an air contaminant or water vapor in quantities that cause, alone or in reaction with other air contaminants, .

. . [i]njurious effects to human health or safety." The rules do not define what constitutes an "injurious" effect. A common dictionary definition of the term, is "causing or likely to cause damage or harm." Here, MDEQ seeks to rely on sampling results indicating a potential exceedance of the IRSL/SRSL as prima facie evidence of emissions "causing or likely to cause" harm to human health. Viant does not agree.

The IRSL/SRSL establish a conservative, protective threshold of risk based upon long-term exposure to a toxic air compound: The IRSL represents the ambient-air concentration estimated to produce an estimated upper-bound lifetime cancer risk of 1 in 1,000,000. The SRSL represents the ambient-air concentration estimated to produce an estimated upper-bound lifetime cancer risk of 1 in 100,000. And both of these estimated risk thresholds are based on continuous lifetime exposure.

Viant acknowledges that the IRSL and SRSL provide a standard intended to be protective of human health. But Viant does not agree that MDEQ can then reflexively use these standards to demonstrate a per se violation of Rule 901(a) without further demonstration that emissions from the Viant facility are likely to injure human health.

B. Rule 901(a)'s Intent

Nothing in the language of Rule 901(a) suggests that MDEQ intended to incorporate the IRSL/SRSL as the basis for finding a violation of the rule. Had MDEQ intended to make a violation of the IRSL/SRSL levels a per se violation of Rule 901(a), it would have done so expressly. Rather, MDEQ expressly chose another vehicle for implementing and enforcing the IRSL/SRSL—Rule 225.

But Rule 225 applies only to new and modified emission units. *See* Rule 225(1); *see also* Rule 201(1) (requiring a PTI only for new, reconstructed, relocated, or modified process or process equipment with potential to emit certain enumerated air pollutants); MDEQ, Overview of Michigan's Air Toxic Rules ("The IRSL applies only to the new or modified source subject to the permit application."), https://bit.ly/2ssAurT. And neither Rule 225 nor any other provision in MDEQ's Air Pollution Control Rules requires that existing sources obtain a new permit when MDEQ later revises the screening levels for a particular toxic air contaminant.

The requirements of Rule 225 demonstrate that the Agency was explicit when it wanted to incorporate the IRSL/SRSL into its rules. Moreover, had MDEQ intended that Rule 901 incorporate the IRSL/SRSL, it is difficult to see why Rule 225 would be necessary, as all facilities would already be subject to the IRSL/SRSL and there would be no need to specify when and how it applies to new or modified facilities.

As Viant has expressed, Viant is also willing to discuss additional, voluntary measures to reduce EtO emissions from the Viant facility. But Viant objects to MDEQ's reliance on Rule 901(a) as a means to attempt to impose new—and significantly stricter—screening levels on an existing, permitted source such as the Viant sterilization facility.

C. MDEQ's Canister-Sampling Methodology

MDEQ conducted one 24-hour, canister-sampling survey at the Viant sterilization facility on November 29–30, 2018. Prior to conducting the survey, MDEQ prepared a brief single-page study

design. Viant understands MDEQ's desire to collect information quickly, but has concerns with the rigor of the MDEQ study and the resulting validity of the results as a method for demonstrating non-compliance with the IRSL/SRSL.

As MDEQ is fully aware, the IRSL/SRSL establish ambient-air thresholds for toxic air compounds. Determining whether a source is in compliance, or will comply, with the IRSL/SRSL requires a combination of air modeling and sampling. In particular, canister sampling, like that conducted by MDEQ, can be used to help verify and inform the dispersion modeling inputs used to determine potential ambient air impacts on surrounding residential areas from toxic-air-compound emissions. When used this way, canister sampling should be conducted according to a rigorous monitoring plan that takes into account specific siting considerations. For example, EPA is currently conducting ongoing EtO sampling at the Sterigenics sterilization facility in Willowbrook, IL. The sampling is being conducted at eight strategically-chosen sites. *See* EPA Region 5 , Quality Assurance Project Plan for Field Sampling Plan for Ambient Air Ethylene Oxide Monitoring Near Sterigenics Facility, Willowbrook, IL, at 11–12 (Nov. 17, 2018), https://bit.ly/2RY8fQp. In determining the sampling locations, EPA consulted the siting criteria identified in 40 CFR § 58, Appendix E (Probe and Monitoring Path Criteria for Ambient Air Quality Monitoring). *Id.* at 16. EPA also took into consideration the dispersion model for the facility, community input, and representative seasonal wind data. *Id.* at 11–12. And EPA expressly noted that because "cigarette or tobacco smoke and vehicle exhaust are additional potential sources of [EtO] . . . special attention and consideration [must] be made to avoid sampling those biasing emission sources." *Id.* at 32. In addition, EPA considered a 90-day sampling period given a 1-in-3-day sampling schedule as a minimum duration to provide sufficient samples to draw meaningful conclusions, and the collection of onsite meteorological data to evaluate whether sample locations were downwind from the site to be potentially attributable to facility emissions. *Id.* at 16. Ultimately, EPA identified the following general location sites as appropriate for sampling:

- Two locations at the maximum ambient air receptors in close proximity to the facility;
- Three locations in residential neighborhoods potentially impacted by the perimeter of the dispersion modeling field and/or located in the predominant downwind direction during the monitoring period; and
- Three locations in residential neighborhoods as selected by the communities (these locations are outside the dispersion modeling field where impact is expected).

Id. at 12.

MDEQ's single 24-hour sampling survey contains none of the rigor of the EPA plan described above. MDEQ used four sampling sites: one site was directly outside the scrubber and shipping room vent; two sites were located on company property in the parking lot outside the facility; and a fourth site was located just outside company property between a nearby sidewalk and street. Further, MDEQ does not appear to take into consideration how background levels of EtO potentially affected the sampling results. For example, a comprehensive sampling study recently conducted by the environmental consulting firm Ramboll showed that average background EtO levels across the Chicago area ranged from 0.19 to 0.28 ug/m^3. The upper-end background levels detected ranged from 0.4 to 1.10 ug/m^3. *See*

https://bit.ly/2CHRD5w. MDEQ has stated its intent to conduct an additional phase(s) of canister sampling to monitor ambient air levels of EtO in the areas surrounding the Viant facility. Viant believes that this additional sampling is necessary to accurately assess Viant's potential impact on ambient EtO levels, and that these studies should be conducted in accordance with the survey methods utilized by EPA.

Accordingly, based on the above, Viant does not believe that the MDEQ sampling results accurately represent the ambient air quality impacts of EtO from the Viant facility and thus do not—standing alone—constitute the proper basis for a Rule 901(a) violation.

III. Conclusion

Viant understands MDEQ's concerns regarding the potential health effects of EtO emissions. As stressed above, Viant is committed to continuing to work with MDEQ to identify additional measures through which Viant can further reduce EtO emissions from the facility. Viant does not agree, however, that MDEQ's proposed violation under Rule 901(a) is consistent with the language or intent of the regulation, and that MDEQ can rely on the Rule to enforce a standard that applies only to new or modified facilities. Additionally, Viant has concerns with the limited sampling data that serves as the basis for the alleged violation and believes a more rigorous and thorough sampling program is necessary to accurately determine the facility's impact on ambient EtO levels.

We look forward to discussing the above with MDEQ and continuing to work cooperatively to resolve this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,

Tricia L. Albert

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