



October 18, 2023

EGLE AQD Warren District
27700 Donald Court
Warren, MI 48092
Attn: Ms. Noshin Khan

Re: B2329 Notice of Violation Response

Dear Ms. Khan:

On 02AUG2023, the Department of Environment, Great Lakes and Energy (EGLE) conducted an inspection of Par Sterile Products ("Par"), LCC located at 870 Parkdale Road, Rochester Michigan. The purpose of this inspection was to determine Par's compliance with the requirements of the federal Clean Air Act; Part 55, Air Pollution Control, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (Act 451); the Air Pollution Control Rules; and the conditions of Permit to Install (PTI) number 73-21. Par claims Rule 290 Permit to Install exemption; therefore, Permits to Install are not obtained for all combustion equipment required by Rule 201. A Notice of Violation (NOV) was issued on 28SEP2023 stating that Rule 290 exemption did not apply for Par due to Hazard Air Pollutants (HAPs) with initial threshold screen levels (ITSLs) exceeding the 20 lbs./month limit, specifically for formaldehyde and manganese.

Par maintains that the Rule 290 Permit to Install Exemption does apply to the facility. Monthly emissions of HAPs (ITSLs) are below the 20 lbs./month limit as required by Rule 290. Actual monthly HAP emissions for formaldehyde and manganese do not exceed 10.0 lbs./month and 0.25 lbs./month respectively. Potential HAP emissions for formaldehyde and manganese are calculated at less than 0.142 tons/year and 0.0001 tons/year respectively. To support compliance with Rule 290, the following documentation is provided to Ms. Noshin Khan:

- List of combustion equipment at Par
- HAP Emissions Monthly Tracking Spread Sheet
- HAP calculations for actual emissions from combustion equipment

We believe that you find the above initial response satisfactory. Par remains committed to maintaining regulatory compliance at the facility. We would appreciate an opportunity to provide any additional information to resolve and remaining issues that you may have after reviewing this response. Should you have any questions or comments, please contact me at (248) 656-5370 or via email at sommers.annette@endo.com.

Sincerely,

Annette Sommers
Director, Global EHS

cc.

Jenine Camilleri (EGLE)
Michael Randolph (Par)