



GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF
ENVIRONMENT, GREAT LAKES, AND ENERGY
WARREN DISTRICT OFFICE



PHILLIP D. ROOS
DIRECTOR

September 28, 2023

Paula Del Papa
Par Sterile Products, LLC
870 Parkdale Road
Rochester, MI 48307

SRN: B2329, Oakland County

Dear Paula Del Papa:

VIOLATION NOTICE

On August 2, 2023, the Department of Environment, Great Lakes, and Energy (EGLE), Air Quality Division (AQD), conducted an inspection of Par Sterile Products, LLC located at 870 Parkdale Road, Rochester, Michigan. The purpose of this inspection was to determine Par Sterile Products' 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.

During the inspection, staff observed the following:

Process Description	Rule/Permit Condition Violated	Comments
Manufacturing activities claimed exempt under Rule 290	Michigan Air Pollution Control Rule 201	The emissions calculations provided indicate a Rule 290 emission limit exceedance.

During this inspection, it was noted that Par Sterile Products had installed and commenced operation of an unpermitted process at this facility. The facility provided calculations claiming the Rule 290 exemption for this process. However, emissions for formaldehyde and manganese exceeded the 20 lb/month limit required for the process to qualify for the exemption.

A program for compliance may include a completed PTI application for the manufacturing process. An application form is available by request, or at the following website:
www.michigan.gov/air.

Be advised that Rule 201 requires that a permit be obtained prior to installation, construction, operation, reconstruction, relocation, or alteration of any process or process equipment which may be a source of an air contaminant.

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Please initiate actions necessary to correct the cited violation and submit a written response to this Violation Notice by October 19 (which coincides with 21 calendar days from the date of this letter). The written response should include: the dates the violation occurred; an explanation of the causes and duration of the violation; whether the violation is ongoing; a summary of the actions that have been taken and are proposed to be taken to correct the violation and the dates by which these actions will take place; and what steps are being taken to prevent a reoccurrence.

Please submit the written response to Noshin Khan at EGLE, AQD, Warren District, at 27700 Donald Court, Warren, Michigan 48092 or KhanN5@michigan.gov and submit a copy to Jenine Camilleri, Enforcement Unit Supervisor at EGLE, AQD, P.O. Box 30260, Lansing, Michigan 48909-7760.

If Par Sterile Products believes the above observations or statements are inaccurate or do not constitute violations of the applicable legal requirements cited, please provide appropriate factual information to explain your position.

Thank you for your attention to resolving the violation cited above and for the cooperation that was extended to me during my inspection of Par Sterile Products, LLC. If you have any questions regarding the violation or the actions necessary to bring this facility into compliance, please contact me at the number listed below.

Sincerely,



Noshin Khan
Environmental Engineer
Air Quality Division
586-536-1197

cc: Annette Sommers, Par Sterile Products
Annette Switzer, EGLE
Christopher Ethridge, EGLE
Brad Myott, EGLE
Jenine Camilleri, EGLE
Joyce Zhu, EGLE