

DEPARTMENT OF ENVIRONMENTAL QUALITY
AIR QUALITY DIVISION
ACTIVITY REPORT: On-site Inspection

U63240612474215

FACILITY: Lumigen, Inc.		SRN / ID: U632406124
LOCATION: 22900 Eight Mile Road		DISTRICT: Warren
CITY: Southfield		COUNTY: OAKLAND
CONTACT: Chuck Endreszl , Staff Quality Assurance Scientist		ACTIVITY DATE: 10/11/2024
STAFF: Adam Bogнар	COMPLIANCE STATUS: Compliance	SOURCE CLASS:
SUBJECT: Scheduled Inspection		
RESOLVED COMPLAINTS:		

On Friday, October 11, 2024, Michigan Department of Environment, Great Lakes, and Energy-Air Quality Division (EGLE-AQD) staff, I, Adam Bogнар conducted a scheduled inspection of Lumigen (the “facility”) located at 22900 Eight Mile Road, Southfield, MI 48033. The purpose of this inspection was to determine the facility’s compliance status with the Federal Clean Air Act; Article II, Part 55, Air Pollution Control of Natural Resources and Environmental Protection Act, 1994 Public Act 451; and Michigan Department of Environment, Great Lakes, and Energy, Air Quality Division (EGLE-AQD) rules.

I arrived at Lumigen at 9 am. I met with Chuck Endreszl, Staff Quality Assurance Scientist, and Mark Sandison, PHD. I introduced myself and stated the purpose of the inspection. We sat down and held a pre-inspection meeting where we discussed operations and looked at the floor plan of the facility. We inspected the manufacturing plant after this meeting.

Lumigen is one of the world’s largest suppliers of chemiluminescent reagents to the clinical immunodiagnosics market. These reagents are used to detect a number of different biological markers in a human sample. In short, the reagents are combined with a sample and will undergo an enzymatic reaction to produce light. The amount of light produced can detect the presence and concentration of certain compounds such as troponins, thyroid compounds, and viral RNA. During the Covid-19 pandemic, these reagents were used to detect the presence of viral COVID-19 RNA.

The facility is operated between 8:30 am and 5:30 pm. There are approximately 37 employees. Lumigen is owned by Beckman Coulter, which is a subsidiary of Danaher.

The chemiluminescent reagent “Lumiphos 530” makes up approximately 90% of the manufacturing that takes place at this facility. This reagent is used in approximately 3 billion tests annually. The actual tests are manufactured by Beckman Coulter – Lumigen only makes the reagent(s). Lumiphos 530 is not manufactured during the summer months due to humidity interfering with the reaction. Other reagents are manufactured periodically based on customer needs.

The main reaction in this process, and the largest reaction that takes place at this facility, is done in a 200L (53 gallon) glass/stainless steel reactor. There are two of these reactors at this facility, located right next to each other. The rest of the manufacturing process is done in small lab benchtop operations.

The facility is not a large open warehouse – it is divided into 20-30 separate laboratories, a few chemical storage areas, a waste storage area, a boiler room, and several other areas. All chemical storage areas I observed were well organized with no open containers.

Laboratory Operations

The laboratory operations at this facility mainly utilize THF, ethyl acetate, acetone, methanol, pyridine, and smaller amounts of other chemicals. Chuck stated that there is not a process at the facility where solvent is purposely evaporated into the atmosphere. All solvent used is either recaptured through distillation (roto-vap or standard condenser), captured in a cold trap of a vacuum pump, or escapes the building as fugitive emissions. Waste solvent is taken away by Viola. Most of the labs are equipped with fume hoods. The fume hoods are ducted out the roof through one of several common exhaust ducts. Based on my observations during this inspection, the laboratory equipment is exempt from Rule 201 requirements pursuant to Rule 283(2)(b). The largest reactors at the facility are approximately 53-gallons in size, which is essentially “pilot” sized, or even smaller. The other laboratory equipment I saw was approximately 1-10 gallons in size. The vacuum pumps are exempt from Rule 201 requirements pursuant to Rule 285(2)(h). The solvent recovery operations are exempt from Rule 201 requirements pursuant to Rule 285(2)(u).

Laboratory glass is mainly cleaned with hot water and soap. Occasionally, an organic solvent will be used to clean glass/equipment. Staff will dispense the organic solvent from a small bottle and wipe down glass/equipment. There are no cold cleaners at this facility.

Boilers

There are two identical Bryan boilers. Both are 2MM BTU/hr heat input. Based on my observations, these boilers are exempt from Rule 201 requirements pursuant to Rule 282(b)(i) since they are used for space heating/water heating and are smaller than 50MM BTU/hr heat input. These boilers are not subject to NSPS Dc – Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units because they have a heat input less than 10MM BTU/hr.

Emergency Generators

The facility operates two emergency generators. One is a Cummins natural gas fired 704kW output generator, which is the primary generator. There is also a 180 kW output diesel generator which is only used as a backup to the natural gas generator. These generators are cycled once per week for preventative maintenance purposes.

The larger 704kW Cummins natural gas generator was installed on March 3, 2004. The smaller 180kW diesel generator was installed on August 30, 2000.

These engines appear to be subject to NESHAP ZZZZ – National Emission Standards for Hazardous Air Pollutants for Stationary Internal Combustion Engines (RICE). EGLE-AQD has not accepted delegation to implement and enforce NESHAP Subpart ZZZZ for area sources of HAP, therefore, compliance with requirements in NESHAP ZZZZ was not evaluated during this inspection.

Both of these emission units were installed prior to the applicability date (January 1, 2009) for NSPS JJJ – Standards of Performance for Stationary Spark Ignition Internal Combustion Engines. These engines are not subject to these standards.

Assuming a thermal efficiency of 25%, the larger 704kW output engine (1,791,278 BTU/hr output) would have a heat input of 7.16MM BTU/hr. Since both of the emergency engines are less than

10,000,000 BTU/hr heat input, these engines are exempt from Rule 201 requirements pursuant to Rule 282(2)(a).

3D Printer

There is a small 3D printer which, based on my observations, is exempt from Rule 201 requirements pursuant to Rule 286(2)(a).

Compliance Determination

Based on my findings during this inspection, Lumigen is operating in 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); Michigan Department of Environment, Great Lakes, and Energy-Air Quality Division (EGLE-AQD) Administrative Rules.

NAME Adam Bogner

DATE 10/23/2024

SUPERVISOR Joyce