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

| N568873096 | | | | |
|--|-------------------------------|---------------------------|--|--|
| FACILITY: Perrigo Holland, Inc. | | SRN / ID: N5688 | | |
| LOCATION: 13295 Reflections Drive, HOLLAND | | DISTRICT: Grand Rapids | | |
| CITY: HOLLAND | | COUNTY: OTTAWA | | |
| CONTACT: Tom Joelson , EHS Senior Manager | | ACTIVITY DATE: 08/13/2024 | | |
| STAFF: Chris Robinson | COMPLIANCE STATUS: Compliance | SOURCE CLASS: MINOR | | |
| SUBJECT: FY '24 Inspection to determine compliance status with respect to PTI 124-11D and any other applicable air quality rules and | | | | |
| regulations. | | | | |
| RESOLVED COMPLAINTS: | | | | |

I. Introduction

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On August 13, 2024, staff Chris Robinson (CR) from Michigan's Department of Environment, Great Lakes, and Energy (EGLE) Air Quality Division (AQD) conducted an onsite inspection at Perrigo (SRN N5688) located at 13295 Reflections Drive, Holland, Michigan. Prior to entry CR surveyed the perimeter of the facility for odors and visible emissions, none were observed. Weather conditions were approximately 68°F, fair sky conditions with north-northeast winds at approximately 7 mph (www.weatherunderground.com).

CR met with Nick Miedema, EHS Senior Manager, and Tom Joelson, EHS Senior Engineer. The purpose of the inspection was relayed, which was to determine this facility's compliance status with respect to applicable state and federal air quality rules and regulations including Permit-To-Install (PTI) 124-11D. Identification was also provided.

II. Facility Description

Perrigo is a manufacturer of over-the-counter medications. The facility receives raw material and blends them together. The blended medication can be either encapsulated or compressed into a pill, some of which are coated.

There are multiple production lines which are assembled per batch and can run for various lengths of time before being disassembled. Most of the processes follow a relatively similar flow through the facility, though each product may vary slightly. Perrigo utilizes some combination of material storage, blenders, weigh rooms, multiple blending suites, tablet presses, encapsulation units and pill coating lines. Multiple points of material handling are controlled by 22 various permitted, exempt and internally vented dust pollution control devices.

The storage area primarily consists of shipping and receiving and a large warehousing area. Most of the materials were received in containers or large totes. Multiple Weigh rooms are used to weigh raw materials prior to blending. They utilize a DC-12 down flow booth to control dust which is exhausted externally. DC-12 is permitted under PTI 124-11D. Blending suites are set up per job to blend the material weighed in the Weigh rooms. Dust is controlled by dust collectors. Once blended the medication is either encapsulated or pressed into a tablet. Some of the blended medication is packaged into containers as a loose powder.

Perrigo's tablet process uses a two-story system of hoppers, loading ports and a press. The system loads the medication powder into the press, then presses it into a pill shape. Any excess dust is collected and controlled. The encapsulation process is similar except instead of pressure the medication is loaded into a capsule which is then sealed with a safety band. The compressed pills

are coated in a large rotary drum that utilizes multiple spray nozzles mounted on a bracket. As the pills tumble, they are sprayed with a coating. Any overspray is minimalized in order to maintain product quality. Dust in the system from potential overspray or product breakage is controlled by a dust collector.

III. Compliance Evaluation

Perrigo is considered to be a minor source of air contaminants and is not subject to the Title V program. The facility's emission units are currently permitted under PTI-124-11D.

A) PTI-124-11D FGPRODUCTION

FGPRODUCTION includes four (4) fluid bed granulators (EUFLUIDBED, EUFLDBDGRANULTR, EUFBG#2 and EUFBD#4) used to dry material; One (1) dry powder granulator; Six (6) film coaters (EUACP-3 through EUACP-8) for coating tablets; four (4) cannister type dust collectors (EUDC#12, EUDC#23, EUDC#24, and EUFBD#3) for various processes; four (4) cartridge dust collectors (EUDC#13, EUEQ#12, EUEQ#38, & EUEQ#45) for various processes; and equipment for mixing (EU300MIXERDC#11) ingredients, compressing powder into tablets (EUEQ-13), and for packaging powder into bottles (EULINE6DC#15).

FGPRODUCTION is subject to twenty-two different pound per hour emission rate limits for particulate matter (PM). The emission rate is listed per emission unit in the table below. The emission rates are low, and the expected control efficiency is relatively high. The following emissions are presumed to be met based on equipment design and regular maintenance.

| Pollutant | Limit | Equipment | Pollutant | Limit | Equipment |
|-----------|----------------|-----------------|-----------|------------|-----------|
| 1. PM | 0.0000165 pph | EUFLUIDBED | 12. PM | 0.56 pph | EUEQ-13 |
| 2. PM | 0.17 pph | EUACP-3 | 13. PM | 0.0265 pph | EUFBG#2 |
| 3. PM | 0.018 pph | EUACP-4 | 14. PM | 0.0108 pph | EUDC#12 |
| 4. PM | 0.018 pph | EUACP-5 | 15. PM | 0.0054 pph | EUDC#23 |
| 5. PM | 0.018 pph | EUACP-6 | 16. PM | 0.0144 pph | EUDC#24 |
| 6. PM | 0.018 pph | EUACP-7 | 17. PM | 0.025 pph | EUFBD#3 |
| 7. PM | 0.018 pph | EUACP-8 | 18. PM | 0.025 pph | EUFBD#4 |
| 8. PM | 0.018 pph | EU300MIXERDC#11 | 19. PM | 0.0026 pph | EUDC#13 |
| 9. PM | 0.0108 pph | EULINE6DC#15 | 20. PM | 0.0032 pph | EUEQ#38 |
| 10. PM | 0.0108 pph | EUGRANULATOR | 21. PM | 0.0072 pph | EUEQ#12 |
| 11. PM | 0.00000477 pph | EUFLDBDGRANULTR | 22. PM | 0.0037 pph | EUEQ#45 |

The facility has various limits depending on the compound that is used and what control device it is being emitted from. The facility is required to limit the usage in FGPRODUCTION of each raw material that is a toxic air contaminant (TAC) such that the ratio of the amount of each raw material that is a TAC used to the total raw material usage does not exceed the ratio of the allowable concentration to the predicted ambient impact, based on a 12-month rolling time period, as determined at the end of each calendar month, as described by the following equation:

Equation 1: RMR = AC/PAI, where

RMR = allowed raw material ratio for each raw material (raw material usage/total raw material throughput)

AC = allowable concentration (AQD screening level or value from the table below if there is no AQD screening level for the raw material)

PAI = predicted ambient impact for total PM, as listed below for each averaging time

1-hour PAI = 54.34 μ g/m³ 3-hour PAI = 36.48 μ g/m³ 8-hour PAI = 31.11 μ g/m³ 24-hour PAI = 16.75 μ g/m³ Annual PAI = 2.61 μ g/m³

| Raw Material | Allowable Conc. (µg/m3) | Averaging Time |
|------------------------------------|-------------------------|----------------|
| Acetaminophen | 15 | Annual |
| Dicalcium phosphate, anhyd gran | 1.0 | |
| Maltodextrin | | |
| Aspirin | | |
| Orange flavor base | | |
| Sugar free orange flavor base | | |
| Cal Carb 95A |] | |
| IM Citrucel Prep Granulation 34817 | | |
| Microcrystalline cellulose 101 | | |
| Naproxen Sodium | 12.0 | |
| Microcrystalline cellulose 102 | 1.0 | |
| Methocel XD | | |
| Methocel A4M Premium | | |
| Ascorbic acid | | |
| Oat fiber granulation | | |
| Calcipure 95A | | |
| Vitamin E acetate | | |
| IM Citrucel Prep Granulation 34818 | | |
| Mannitol | 42.0 | 1 hour |

The provided

emissions report summarized the data using the above equation to include a maximum RMR along with an Actual RMR and a pass/fail notation. No emissions were reported in exceedance of the allowable RMR. The facility appears to be complying with the material limits of PTI 124-11D.

The permittee is required to not operate the emission units listed in the permit unless the associated control equipment is installed, maintained, and operated in a satisfactory manner. Proper operation of each of the dust collectors includes submitting an operation and maintenance plan which has been submitted. All dust collectors are equipped with differential pressure gauges as required. Dust collector inspection and corrective action records are required to be kept which were reviewed onsite. None of the coaters or granulators were operating during the inspection nor were their associated dust collectors. The Line 13, dust collector had a DP of 1.99 inches of water column (w.c.). The dust collectors for EUDC23 and EUEQ45 were operating with DP of 0.64" w.c and 0.99" water column. The remaining dust collectors were either not operating or observed through a viewing area. Therefore, DP readings could not be taken. The area around all of dust collectors was very clean and they appeared to be well maintained. Stack measurements were not explicitly measured however, based on observations appeared to meet the requirements specified in the PTI.

Except as allowed in the PTII for stacks SVFLUIDBED, SVAA, SV15, SV21, SV13, all stacks appeared to be discharged unobstructed vertically to ambient air.

B) Other

The facility uses two 23 MMBTU per hour natural gas fired Clever Brooks boilers exempt from Rule 201 permitting requirements per Rule 282(2)(b)(i). These boilers are subject to 40 CFR Part 60 Subpart Dc Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units. Fuel usage is being tracked.

Line 13 is a powder packaging line installed in 2021 under Rule 201 permitting exemption Rule 290. PM emissions are controlled by a dust collector. In order to use Rule 290 for PM emissions the baghouse must have a flow rate of not more than 30,000 acfm and be designed to control PM emissions to a concentration of less than or equal to 0.01 pounds of particulate per 1,000 pounds of exhaust gas. The exact rating of the dust collector is unknown but based on observations it is well under 30,000 cfm. Since it is being maintained and operated properly the facility appears to be meeting the required concentration.

C) Annual Emissions Inventory

Perrigo reports emissions annually. Their 2023 emissions are summarized below.

| Pollutant | Amount (tons) | Pollutant | Amount (tons) |
|-----------|---------------|-----------|---------------|
| СО | 5.14 | PM25-FIL | 0.12 |
| Lead | 0.00003 | PM-CON | 0.35 |
| NOX | 6.12 | SO2 | 0.04 |
| PM10-PRI | 1.95 | VOC | 0.34 |
| PM10-FIL | 0.12 | NH3 | 0.20 |
| PM25-PRI | 0.46 | | |

IV. Compliance Determination

Based on observations, discussions, and a records review, Perrigo appears to be operating in compliance with applicable air quality rules and regulations including PTI 124-11D.

NAME

DATE 8/29/2024

SUPERVISOR