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

B727664558

FACILITY: L PERRIGO CO		**SRN / ID:** B7276
LOCATION: 515 EASTERN AVENUE, ALLEGAN		**DISTRICT:** Kalamazoo
CITY: ALLEGAN		**COUNTY:** ALLEGAN
CONTACT: Tom Joelson , Senior EHS Engineer		**ACTIVITY DATE:** 07/21/2022
STAFF: Cody Yazzie	**COMPLIANCE STATUS:** Compliance	**SOURCE CLASS:** MINOR
SUBJECT: Scheduled Inspection		
RESOLVED COMPLAINTS:		

On July 21, 2022 Air Quality Division (AQD) staff (Cody Yazzie) arrived at 655 Hooker Road, Allegan Michigan at 10:00 AM to conduct an unannounced air quality inspection of Perrigo Company (hereafter Perrigo) SRN (B7276). Staff made initial contact with the Security Team located at the Security Office on the North side of the Perrigo Campus and stated the purpose of the visit. Tom Joelson, Perrigo, Senior EHS Engineer, is the environmental contact and arrived shortly thereafter and took staff to a conference room for further discussions.

Perrigo is a manufacturer of pharmaceutical over the counter medications. The medications are in tablet form. The facility operates three shifts for operation 24 hours per day and 7 days a week. This stationary source has a large campus that includes the EAO Office building, Plant4, Plant 5, Plant 7, and the Security Building. The facility also has other office building on the west side Eastern Avenue. The facility has around 3500 employees that work on the campus.

Perrigo was last inspected by the AQD on August 1, 2018 and appeared to be in non-compliance at that time with PTI No. 416-93F and 208-89C. Staff asked, and Mr. Joelson stated that the facility does have boilers and emergency generators that were installed under an exemption.

Mr. Joelson gave staff a tour of the facility. Required personal protective equipment are safety glasses, steel toe boots, lab coat, boot covers, hair cover, and hearing protection. Staff observations and review of records provided during and following the inspection are summarized below:

PTI No. 416-93J (Plant 4):

Plant 4 and 5 operations have similar process flows and manufacturing steps. Plant 4 has the addition of the granulations step. Plant 4 will receive raw materials that get mixed and measured before granulation. After granulation, the facility will compress the formulated tablets into their desired shape. Coating and packaging follow to produce the products. The emission units permitted have naming conventions that reflect what portion of the manufacturing process they control/serve.

EU4DUSTCOLL7:

This emission unit has special conditions in which specify what the types of material that should not be used in EU4DUSTCOLL7. These restrictions are outlined in Special Conditions I.1.a-c and have to do with the evaluated screening levels which would be less than the predicted ambient impacts in Appendix A.

To show compliance with these material limits the facility is required to maintain monthly records that record all the material processed in EU4DUSTCOLL7. There is a list of Toxic Air Contaminants (TACs) that were evaluated during the PTI process that have been evaluated included in Appendix A of PTI No. 416-93J that meet the material limit specifications. For any TAC that is not listed in the appendix that the facility wants to use the facility should use either a PTI Rule 201 exemption, use the material if the material has an established AQD Screening Level that is greater than the predicted ambient impacts shown in Appendix A, or the facility can make a request to the AQD for a toxic's determination. Staff reviewed the monthly records for the following months: July 2021, September 2021, November 2021, January 2022, March 2022, and June 2022.

During the review EU4DUSTCOLL7 had a several materials that were not included in Appendix A, Staff could not find an established AQD Screening Level, and there has been no toxic determination request by the facility. The facility would be needing to use a PTI exemption to use the additional material not listed in Appendix A. Staff has requested the exemption demonstrations. Pending the demonstrations the facility would appear to be in compliance with the materials limits and keeping the required recordkeeping.

Below is the list of materials that when reviewed Staff needed the PTI demonstrations for.

Material/Ingredient	CAS#	AC	Avg. Time
• BLUE #1 FD&C	3844-45-9	0.1	Annual
• Carbopol 974P	9003-01-4	0.1	Annual
• FEXOFENADINE HCL	153439-40-8	0.1	Annual
• FEXOFENADINE HCL	138452-21-8	0.1	Annual
• Opadry YS-1-7006		0.1	Annual
• OPDARY PINK II 85F140116		0.1	Annual
• PSEUDOEPHEDRINE SULFATE	7460-12-0	0.1	Annual
• HYDROXYETHYL CELLULOSE	9004-62-0	0.1	Annual
• SYLOID 244 FP	7631-86-9	0.1	Annual
• Cool Mint Flavor, Nat & Art	Multiple	0.1	Annual
• OPADRY II 85F93084 ORANGE		0.1	Annual
• OPADRY YS-1-9012		0.1	Annual
• STEARIC ACID 112-84-5		0.1	Annual
• YELLOW #10 D&C LAKE	68814-04-0	0.1	Annual
• BLUE #1 FD&C 68921-42-6		0.1	Annual
• STARCH 9005-25-8		0.1	Annual
• YELLOW #6 FD&C	15790-07-5	0.1	Annual

Staff did notice that there were some inconsistencies in the recordkeeping and Appendix A's listed allowable concentrations. Staff noticed that Acetaminophen (CAS# 103-90-2) had a listed allowable concentration of 15 in the monthly recordkeeping, while Appendix A had the allowable concentration listed as 12. This is likely due to the facility using 15 as a part of the FGPLANT4 records. Cabosil M-5 (CAS# 112945-52-5) was recorded as having an allowable concentration of 0.1 with an averaging period of annual in the monthly recordkeeping. Cabosil M-5 in the PTI appendix A has an allowable concentration of 60 with an averaging period of 8 hours. Croscarmellose NA (CAS# 74811-65-7) was recorded as having an allowable concentration of 0.1

with an averaging period of annual in the monthly recordkeeping. Croscarmellose NA in the PTI appendix A has an allowable concentration of 12 with an averaging period of annual. Dextromethorphan (CAS# 6700-34-1) was recorded as having an allowable concentration of 0.1 with an averaging period of annual in the monthly recordkeeping. Dextromethorphan in the PTI appendix A has an allowable concentration of 0.4 with an averaging period of annual. Ibuprofen (CAS# 15687-27-1) was recorded as having an allowable concentration of 15 with an averaging period of annual in the monthly recordkeeping. Ibuprofen in the PTI appendix A has an allowable concentration of 12 with an averaging period of annual. Guaifenesin (CAS# 93-14-1) was recorded as having an allowable concentration of 0.1 with an averaging period of annual in the monthly recordkeeping. Guaifenesin in the PTI appendix A has an allowable concentration of 5 with an averaging period of annual.

Staff mentioned to Mr. Joelson that the facility should use what is listed in the appropriate appendix for the records. The inconsistencies do not appear to affect compliance as the materials are evaluated in the appendix and above the predicted impacts outlined in the appendix. Staff suggested that including where the values for the allowable concentrations came from for each material used would be a helpful addition to the records. This would help the AQD identify easier if the material were evaluated initially and included in the appendix, the facility submitted a toxic determination, or if the facility determined in a PTI exemption that the material was acceptable to use.

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

EU4DUSTCOLL7 was operating during the inspection. Staff took a differential pressure reading from the dust collector. Staff noted during the inspection that the differential pressure was 2.5 inches of water, which is within the typical operating range of the unit.

EUDUSTCOLL8:

This emission unit has special conditions in which specify what the types of material that should not be used in EUDUSTCOLL8. These restrictions are outlined in Special Conditions I.1.a-c and have to do with the evaluated screening levels which would be less than the predicted ambient impacts in Appendix B.

To show compliance with these material limits the facility is required to maintain monthly records that record all of the material processed in EUDUSTCOLL8. There is a list of TACs that were evaluated during the PTI process that have been evaluated included in Appendix B of PTI No. 416-93J that meet the material limit specifications. For any TAC that is not listed in the appendix that the facility wants to use the facility should use either a PTI Rule 201 exemption, use the material if the material has an established AQD Screening Level that is greater than the predicted ambient impacts shown in Appendix B, or the facility can make a request to the AQD

for a toxic's determination. Staff reviewed the monthly records for the following months: July 2021, September 2021, November 2021, January 2022, March 2022, and June 2022.

During the review of EUDUSTCOLL8 there were two materials that were not included in Appendix B, and Staff could not find an established AQD Screening Level, but Perrigo did submit a toxic determination request to the AQD that included the material. From the review the facility appears to be complying with the recordkeeping and material limit requirements included in PTI No. 416-93J. These two materials are listed below.

Material/Ingredient	CAS#	AC	Avg. Time
• Opadry YS-1-7006		0.1	Annual
• Starch	9005-25-8	0.1	Annual

Staff did notice that there were some inconsistencies in the recordkeeping and Appendix B allowable concentrations. Staff noticed that Starch (CAS# 9005-25-8) had a listed allowable concentration of 0.1 with an averaging period of annual. This material has two allowable concentrations for two different averaging periods. In the May 23, 2022 the facility requested a Toxics Determination letter, which the materials were accepted at having an allowable concentration of 12 for the annual averaging period and 35 for the 24-hour averaging period.

Staff mentioned to Mr. Joelson that the facility should use what is listed in the appropriate appendix or accepted toxics determination request for the records. The inconsistencies do not appear to affect compliance as the materials are evaluated in the appendix or a toxic determination request submitted to the AQD, and above the predicted impacts outlined in the appendix. Staff suggested that including where the values for the allowable concentrations came from for each material used would be a helpful addition to the records. This would help the AQD identify easier if the material were evaluated initially and included in the appendix, the facility submitted a toxic determination, or the facility determined in a PTI exemption that the material was acceptable to use.

As noted previously the facility can request an air toxics determination for materials that are not listed in the Appendix B. If the facility choses to make the request the facility must do so at least 30 days before first using the material. The AQD has received one request for toxic determinations for this emission unit. This determination was requested on May 23, 2022. The toxic determinations were approved using the proposed screening levels in the request.

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

EUDUSTCOLL8 was not operating during the inspection. The operations it controls are on a batch basis so there are times when the dust collector is not operating, because the equipment it controls is not operating.

EU4GLATT500#5

This emission unit has special conditions in which specify what the types of material that should not be used in EU4GLATT500#5. These restrictions are outlined in Special Conditions I.1.a-c and have to do with the evaluated screening levels which would be less than the predicted ambient impacts in Appendix C.

To show compliance with these material limits the facility is required to maintain monthly records that record all the material processed in EU4GLATT500#5. There is a list of TACs that were evaluated during the PTI process that have been evaluated included in Appendix C of PTI No. 416-93J that meet the material limit specifications. For any TAC that is not listed in the appendix that the facility wants to use the facility should use either a PTI Rule 201 exemption, use the material if the material has an established AQD Screening Level that is greater than the predicted ambient impacts shown in Appendix C, or the facility can make a request to the AQD for a toxic's determination. Staff reviewed the monthly records for the following months: April 2022 and June 2022. The equipment for this emission unit did not begin production until April 2022.

During the review of EU4GLATT500#5 there were three materials that were not included in Appendix C, and Staff could not find an established AQD Screening Level, but Perrigo did submit a toxic determination request to the AQD that included the material. From the review the facility appears to be complying with the recordkeeping and material limit requirements included in PTI No. 416-93J. These three materials are listed below.

Material/Ingredient	CAS#	AC	Avg. Time
• LANSOPRAZOLE	103577-45-3	0.1	Annual
• MEGLUMINE	6284-40-8	0.1	Annual
• METHACRYLIC ACID COPOLYMER	25212-88-8	0.1	Annual

As noted previously the facility has requested an air toxics determination for materials that are not listed in the Appendix C. If the facility choses to make the request the facility must do so at least 30 days before first using the material. The AQD has received two requests for toxic determinations for this emission unit. The determinations were requested on March 15, 2022 and June 1, 2022. The toxic determinations were approved using the proposed screening levels in the request.

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

EU4GLATT500#5 was not operating during the inspection. The operations it controls are on a batch basis so there are times when the dust collector is not operating, because the equipment it controls is not operating.

FGPLANT4:

For the rest of the emission units permitted under PTI No. 416-93J that are not EU4DUSTCOLL7, EUDUSTCOLL8, and EU4GLATT500#5 are covered under FGPLANT4. This flexible group uses equation 1 noted in Special Condition II.1 to verify compliance. This equation uses the ratio of the raw material usage divide by the total raw material throughput. For this Perrigo is tracking both the specific raw material usage on a 12-month rolling time period and the total raw material throughput on a 12-month rolling period. This provides a ratio or RMR in equation 1. The maximum allowable RMR would then be the maximum allowable concentration divided by the Predicted Ambient Impact (PAI). Records should show that RMR calculated through raw material usage data is lower than the maximum allowable RMR.

There are instances where the facility is calculating the maximum allowable RMR to be 1 when the calculation previously mentioned is actually higher. This is due to the fact that RMR based on raw material usage can not be greater than 1, since it is a ratio of the mass of a specific ingredient to the mass of the total production.

Staff requested the 12-month rolling records for the following months: July 2021, September 2021, November 2021, January 2022, March 2022, and June 2022. These records appeared to show that the facility did not exceed any of the Maximum allowable RMR's for the materials/ingredients used. From Staff's review it did appear that the facility was calculating and maintaining the appropriate records based on the reported allowable concentrations and predicted ambient impacts.

Staff did note that there were several materials that were processed through the flexible group but were not in the Table included in Special Condition II.1 or had an established AQD screening Level. Special condition II.1 states that for each raw material that is not listed in the Table and there is no AQD Screening Level, the allowable concentration shall be determined according to Rules 231 and 232. Staff has requested the documentation for these materials to show that Rules 231 and 232 were followed to use the averaging times and allowable concentrations. Pending this submittal and review of documents the facility appears to be in compliance with the material limits.

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

Below is a table that list all the dust collectors in Plant 4 that were observed, and their pressure drop reading from the inspection. Each dust collector observed operating appeared to be operating in the typical operating range.

Emission Unit ID	Dust Collector SAP PM Plan #	Control Device ID	Stack Vent ID	Inspection Observed Differential Pressure (in. H20)
EU4VAC1	9405	VCS401	SVVCS401	7.0
EU4VAC2	9406	VCS402	SVVCS402	0.5
EU4VAC4	9409	VCS404	SVVCS404	1.2
EU4DUSTCOLL1	9404	DCS401	SVDCS401	1.0
EU4DUSTCOLL2	9400	DCS402	SVDCS402	1.5

EU4DUSTCOLL3	9399	DCS403	SVDCS403	6.0
EU4DUSTCOLL4	9397	DCS404	SVDCS404	NO
EU4DUSTCOLL5	9398	DCS405	SVDCS405	NO
EU4DUSTCOLL6	9414	DCS406	SVDCS406	0.8
EU4DUSTCOLL9	9401	DCS409	SVDCS409	NO
EU4DUSTCOLL10	9402	DCS410	SVDCS410	NO
EU4DUSTCOLL11	9403	DCS411	SVDCS411	NO
EU4DUSTCOLL12	9408	DCS412	SVDCS412	5.5
EU4DUSTCOLL14	9410	DCS414	SVDCS414	NO
EU4DUSTCOLL15	9411	DCS415	SVDCS415	4.8
EU4DUSTCOLL16	9134	DCS416	SVDCS416	NO
EU4DUSTCOLL17	11864	DCS417	SV4DUSTCOLL17	NO
EU4DUSTCOLL18	11703	DCS418	SV4DUSTCOLL18	4.0
EU4DUSTCOLL19	11873	DCS419	SV4DUSTCOLL19	1.5
EU4DUSTCOLL22	21355	DCS422	SVDCS422	0.6
EU4DUSTCOLL23	21356	DCS423	SVDCS423	NO
EU4GLATT#3	13984	DCS420	SV4GLATT#3	5.32
EU4CLATT#4	19113	DCS421	SVDCS421	2.5

***** NO indicates that the unit was not in operation during the inspection because equipment it is serving was not in operation.*****

FGPLANT4CLEAN:

This flexible group is for the cleaning activities at plant 4. The facility uses isopropyl alcohol (IPA) for plant cleaning. The facility buys a 99% IPA and 70% IPA for this. The facility is maintaining records of monthly gallons purchased for each. The facility then uses the lbs of VOC/gallon for each IPA to calculate the amount of VOC's per month. The facility is maintaining records for a 12-month rolling of VOC emissions from the cleaning operations. Staff reviewed the emissions records for the time period of January 2021 through June 2022. The highest calculated VOC emissions occurred in January 2021 in which the facility recorded 13.12 TPY of VOC emissions. This is well below the permitted limit of 36 TPY.

PTI No. 208-89D (Plant 5):

Plant 5 is similar to Plant 4 minus the granulation step. Plant 5 will receive raw materials that get mixed and measured before it is compressed to the desired shape. Coating and packaging follow to produce the products. The emission units permitted have naming conventions that reflect what portion of the manufacturing process they control/serve.

EUCOATINGPAN049:

This emission unit has special conditions in which specify what the types of material that should not be used in EUCOATINGPAN049. These restrictions are outlined in Special Conditions I.1.a-c and have to do with the evaluated screening levels which would be less than the predicted ambient impacts in Appendix A.

To show compliance with these material limits the facility is required to maintain monthly records that record all the material processed in EUCOATINGPAN049. There is a list of TACs that were evaluated during the PTI process that have been evaluated included in Appendix A of PTI No. 208-89D that meet the material limit specifications. For any TAC that is not listed in the appendix that the facility wants to use the facility should use either a PTI Rule 201 exemption,

use the material if the material has an established AQD Screening Level that is greater than the predicted ambient impacts shown in Appendix A, or the facility can make a request to the AQD for a toxic's determination. Staff reviewed the monthly records for the following months: July 2021, September 2021, November 2021, January 2022, March 2022, and June 2022.

During the review EUCOATINGPAN049 had a several materials that were not included in Appendix A, Staff could not find an established AQD Screening Level, and there has been no toxic determination request by the facility. The facility would be needing to use a PTI exemption to use the additional material not listed in Appendix A. Staff has requested the exemption demonstrations. Pending the demonstrations, the facility would appear to be in compliance with the materials limits and keeping the required recordkeeping.

Below is the list of materials that when reviewed Staff needed the PTI demonstrations.

Material/Ingredient	CAS#	AC	Avg. Time
• Corn Starch	9005-25-8	0.1	Annual
• Croscarmellose Sodium	74811-65-7	15	Annual
• MICROCRYST CELLULOSE	9004-34-6	15	Annual
• OPADRY YS-1-9012	multiple	0.1	Annual

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

FGPLANT5:

Perrigo is required to maintain 12-month rolling emission records to demonstrate compliance with Special Condition I.1. The facility is maintaining monthly records of PM emissions that are used to calculate 12-month rolling PM emissions. Staff reviewed the emissions records for the time period of January 2021 through June 2022. The highest calculated PM emissions occurred in April 2021 in which the facility recorded 0.01067 TPY of PM emissions. This is well below the permitted limit of 0.35 TPY.

Perrigo is required to maintain 12-month rolling emission records to demonstrate compliance with Special Condition I.8. This emission limit is for IPA use that is for plant 5 cleaning. The facility buys a 99% IPA and 70% IPA for this. The facility is maintaining records of monthly gallons purchased for each. The facility then uses the lbs of VOC/gallon for each IPA to calculate the amount of VOC's per month. The facility is maintaining records for a 12-month rolling of VOC emissions from the cleaning operations. Staff reviewed the emissions records for the time period of January 2021 through June 2022. The highest calculated VOC emissions occurred in January 2022 in which the facility recorded 30.03 TPY of VOC emissions. This is below the permitted limit of 36 TPY.

Perrigo has 12-month rolling VOC and HAP limits for the emission units associated with FGPLANT5. The facility uses powdered products that have water added to them and applied as

coatings. Perrigo provided the SDS of these powder coatings. From Staff review the coatings did not contain any VOC's. The facility also provided a list of all the materials that were used in FGPLANT5 emission units. The list of materials was used to evaluate HAPs that are used at the facility. The records appeared to show that the facility does not process any HAPs through these emission units. The absence of VOC's and HAPs would make emission records 0 for these emissions. Staff indicated that it is Perrigo's responsibility to maintain records if process changes are made that would use VOC or HAP in the emission units. Staff also noted with the lack of VOC and HAP emissions the facility may want to have the PTI modified to represent current operations. Especially with the HAP emissions the facility could install exempt equipment that could cause the facility problems with Potential to Emit and the source categorization in the future.

This flexible group uses equation 1 noted in Special Condition II.1 to verify compliance. This equation uses the ratio of the raw material usage divide by the total raw material throughput. For this Perrigo is tracking both the specific raw material usage on a 12-month rolling time period and the total raw material throughput on a 12-month rolling period. This provides a ratio or RMR in equation 1. The maximum allowable RMR would then be the maximum allowable concentration divided by the Predicted Ambient Impact (PAI). Records should show that RMR calculated through raw material usage data is lower than the maximum allowable RMR.

There are instances where the facility is calculating the maximum allowable RMR to be 1 when the calculation previously mentioned is actually higher. This is due to the fact that the RMR based on raw material usage cannot be greater than 1, since it is a ratio of the mass of a specific ingredient to the mass of the total production.

Staff requested the 12-month rolling records for the following months: July 2021, September 2021, November 2021, January 2022, March 2022, and June 2022. These records appeared to show that the facility did not exceed any of the maximum allowable RMR's for the materials/ingredients used. From Staff's review it did appear that the facility was calculating and maintaining the appropriate records based on the reported allowable concentrations and predicted ambient impacts.

Staff did note that there were several materials that were processed through the flexible group but were not in the Table included in Special Condition II.1 or had an AQD screening Level. Special condition II.1 states that for each raw material that is not listed in the Table and there is no AQD Screening Level, the allowable concentration shall be determined according to Rules 231 and 232. Staff has requested the documentation for these materials to show that Rules 231 and 232 were followed to use the averaging times and allowable concentrations. Pending this submittal and review of documents the facility appears to be in compliance with the material limits.

Perrigo is required to develop and maintain an operation and maintenance (O&M) plan for the dust collector. The facility has an O&M table that correlates with maintenance/inspection schedule that is used to service the dust collectors. Also included are typical operational rangers for the differential pressure across the baghouse. The facility also provided work orders that showed what was serviced during the inspection. This O&M plan appears to meet the requirements of Special Condition IV.1, however if the plan becomes insufficient the facility would need to update the plan to address any deficiencies.

Below is a table that list all the dust collectors in Plant 5 that were observed, and their pressure drop reading from the inspection. Each dust collector observed operating appeared to be operating in the typical operating range.

Emission Unit ID	Dust Collector SAP PM Plan #	Control Device ID	Inspection Observed Differential Pressure Reading (in. H20)
EUCOATING042	21362	DC-515	NO
EUCOATING043	37048	DC-518	NO
EUCOATING044	37047	DC-519	NO
EUCOATING045	9576	DC-505	NO
EUCOATING046	9579	DC-511	3.75
EUCOATING047	9581	DC-512	NO
EUCOATING048	9582	DC-13	NO
EUCOMPRESS1	9587	DC510	3.0
EUCOMPRESS2	9588	DC-514	2.0
EUCOMPRESS3	9061	DC-509	1.0
EUVAC1	9578	DC-508	1.0

***** NO indicates that the unit was not in operation during the inspection because equipment it is serving was not in operation.*****

Plant 6:

Plant 6 is a building that is owned by Perrigo but is leased out to a company named Multi Packaging Solutions. This company makes labels for the Perrigo. The facility has their own Permit to install under PTI No. 225-05D and is given the SRN N6727. Perrigo stated that the management and ownership of the company are separate from the Perrigo Company. These two companies appear to be evaluated as two different stationary sources.

Plant 7:

Plant 7 does have two Rule 291 emission units along with some boilers. Plant 7 is primarily used for packaging and warehouse storage space.

Boilers:

Perrigo has three boilers that are all ducted to the same stack. Perrigo indicated that two of the boilers were installed around 1992 together. Since these were around the same timeframe Staff indicated that they would like to see the PTE for the boilers as the combined maximum heat input rating for the boilers were 62.77 MMBTU/hr. Staff was provided with the PTE for all criteria pollutants for both boilers. The largest PTE was for NOx in which it was calculated that the combined PTE of the boilers are 26.95 TPY of NOx emissions. From this calculation it appears that installing these two boilers together did not exceed the significant levels for the PTE's on the criteria pollutants.

All three boilers appear to be exempt from Rule 201 per Rule 282(2)(b)(i) based on the records provided. The facility has 4-boilers that are installed at Plant 5 and 2-boilers that are installed in Plant 7. These boilers are natural gas firing and have a maximum heat input rating that range from 5.25 MMBTU/hr – 16.74 MMBTU/hr. Installation of these boilers all range from 1973 – 1993. These boilers appear to be exempt per Rule 282(2)(b)(i) as well.

Emergency Generators:

The facility has 10 emergency generators across all the buildings located on the Perrigo campus. The locations of these include EAO Office building, Plant4, Plant 5, Plant 7, and the Security Building. These install dates have been spread out across the years from 1993-2014. The generators vary in maximum heat input rating ranging from 0.59 to 1.89 MMBTU/hr. These appear to meet the exemption requirements of Rule 285(2)(g).

The facility appears to be keeping records of engine hours along with maintenance records for the oil filter changes, hose and filter inspections. The facility appears to be keeping other maintenance records as well.

Bottling Lines Rule 291:

The facility is two Rule 291 lines that utilize equipment that perform the tablet packaging for the bottle filling and blister fill operations. These lines are located in plant 7 and are identified as Line 411 and 424. These Lines are controlled by Torit DCCR2-4 (DC-709) and Torit DFT2-4 (DC-701) respectively. Rule 291 is based on potential to emit so the facility is required to maintain records of the Potential to Emit (PTE) of the emission units.

The facility produced records for PTE of the PM emissions and talc emissions. In the calculations the facility noted that the only TAC identified out of the materials run on the lines that has a screening level lest than 2. For the Rule 291 records the documentations or calculations should include the toxic air contaminant screening level applicable at the time of installation and/or modification of the emission unit. Staff has requested the screening levels for each toxic air contaminate evaluated. Pending this request evaluation, the facility appears to be in compliance with Rule 291 for these emission units.

Air Conditioning Systems Rule 280(2)(b):

The facility has a number of emission units that are air conditioning or comfort ventilation systems. These systems don't appear to be designed for the purpose of removing air contaminants generated or released by a specific emission unit. Mr. Joelson stated that these are ventilation systems that intake general in plant air and filter through the use of a dust collector then exhaust the air back into the general in plant environment. It was indicated that these systems serve portions of the plant and not specific emission units. Mr. Joelson stated that all the filtration systems are used for worker health/comfort.

These units are identified by the following: Plant 5 Liquid Suspension Mix, Plant 5 Liquid Mix, Plant 5 Blending (tablets), Plant 5 Upper Mix (tablets), Plant 5 Tablets – Mix, Plant 5 Tablets – Dispensing, and 4 units that serve the Plant 7 North Mech Room.

Pilot Process Rule 283(2)(a):

The facility operates pilot processes that are used for R&D purposes. It was indicated that Perrigo does not make any of these products for sale. The purpose of the R&D facility is for developing new formulations and evaluating formulation changes. Mr. Joelson estimated that the facility handles around 70 different formulations a year in the facility. The two Plant 4 R&D stations in the Mechanical Space are controlled by dust collectors. These appear to be the units that were evaluated in the 1997 inspection report of the facility. In this inspection report the emission units

mentioned appeared to be in compliance with Rule 283. Since this 1997 inspection report the facility has upgraded the dust collection systems to the DC-408 and VAC-403.

The thermal oxidizer that was installed in 2017 and meant for use when solvent coatings are utilized. The facility does not employ any solvent coatings in their process and have indicated that as of the inspection do not plan to go to solvent coatings any time soon. With no solvent coatings used the Thermal oxidizer has not been used in the pilot process recently. The facility appears to be in compliance with Rule 283(2)(a) for the pilot process.

At the time of the inspection and based on a review of records obtained during or following the inspection, the facility appears to be in compliance with PTI No. 208-89D and PTI No. 416-93J pending the follow up on additional records review. These reviews are for the PTI demonstrations for EU4DUSTCOLL7 and EUCOATINGPAN049. Additional records were also requested for FGPLANT4 and FGPLANT5 for the materials that were not listed in the Special Condition II.1 Table. A record/demonstration should show that Rule 231 or Rule 232 were followed for each material not listed in the tables in Specal Condition II.1 of FGPLANT4 and FGPLANT5. The facility was also requested to provide the specific Rule 291 materials that were evaluated and their screening levels. Staff stated to Mr. Joelson that a report of the inspection would be sent to the facility for their records. Staff concluded the inspection at 5:00 PM.-CJY

NAME Cody Yaryan DATE 9/28/22 SUPERVISOR Annette Closs

Acting DS for Rex Lane