Synthetic Minor Determination and/or ☐ Netting Determination

Permit To Install: 01-12044

A. Source Description

The proposed Fluid Bed / Granulator Dryer is identical to an existing Fluid Bed Dryer (P010, PI#01-06687). The unit includes a functionally identical fluidized bed for pharmaceutical powder processing, a fabric filter and HEPA (high-efficiency particulate air) filter (in series) for particulate capture. Raw materials are measured, mixed and injected into the unit where the batch granulating and drying process takes place. After the batch is completed the fabric filter and HEPA filter are cleaned to avoid potential cross-contamination with other products. The process operates in two modes in series. The granulating mode is when the pharmaceutical powders are mixed with an alcohol (in this case ethanol) to make larger granules for processing. The drying mode drives off any residual alcohol from the granules prior to further processing.

B. Facility Emissions and Attainment Status

This facility is not a major source for PSD applicability purposes and is located in Franklin County, which is non-attainment for PM$_{2.5}$ and ozone.

Boehringer Ingelheim Roxane, Inc. (BIRI) SIC code, 2834, is covered by a NESHAP (40 CFR 63 Subpart GGG, National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production). BIRI is not a major source for HAPs (Hazardous Air Pollutants), with a PTE of less than 10 tons per year of any one HAP (in this case methanol from another air emissions unit) and fewer than 25 tons per year of combined HAPs.

Currently this is not a Title V facility, but it has been issued a FESOP which limits the emissions of organic compounds from four other granulating processes (P006, P007, P008 and P009) to 7.81 tons per year. Three other air emission sources have already been issued Permit Ton Install Synthetic Minors. According to current facility records, the PTE for OC is about 39 tons per year and will increase to about 47 tons per year given the terms of this permit.

The criteria pollutant emitted from this source is PM$_{10}$. This facility utilizes fabric filters and HEPA filters in series for particulate matter control on all sources that process pharmaceutical powders. This filtration scheme is mandated by the DEA and FDA, which require accounting of all pharmaceuticals manufactured at the facility. The PM controls utilized are therefore intrinsic to the process and are an inherent physical limitation for PM emissions.

OAC 37145-21-09(W) does not apply to pharmaceuticals produced at BIRI, which are made by formulation rather than synthesis.

C. Source Emissions

According to the current PTI application, batch time for this air emissions unit is two (2) hours. This includes a 90 minute cycle time and a 30 minute cleaning/preparation period. It is requested in the permit application and accompanying calculations that the permit reflect the potential for 12 batches per day to accommodate short term production demands. See example calculations below:

1. Organic Compound (OC) Emissions

The liquid OC ingredient in the granulating process is ethanol (92.4% wt/wt). Ethanol is not currently defined as a Volatile Organic Compound (VOC), nor is it photochemically reactive. There are no OC
emission controls associated with this air emissions unit. Please note that currently there is only one product that utilizes ethanol that this facility produces. For a majority of the granulating batches, the liquid ingredient is water.

PTE Calculation: No applicable NSPS, MACT, or SIP limitation applies. The emissions are uncontrolled, and assume 100% loss of OC.

12 batches per day * 69 lbs OC / batch = 828 lbs / day (short-term PTE)

12 batches per day * 69 lbs OC / batch * 364 days / year * 0.0005 tons/lb = 150.7 tons / year (annual PTE)

According to the application submitted to BIRI, the process would be limited to their maximum PTE on a daily basis and 240 batches annually. These limitations would allow high daily production rates that may be required based on product orders, while limiting OC emissions on an annual basis. The synthetic minor limitations (voluntary restrictions) will restrict emissions under the 10 tons / year threshold. See example calculations below:

12 batches per day * 69 lbs OC / batch = 828 lbs / day (short-term OC emission limit)

69 lbs OC / batch * 240 batches / year * 0.0005 tons / lb = 8.28 tons / year (annual OC emission limit)

This process will emit > 1 ton / year of a compound with a TLV (ethanol), and therefore triggers Ohio Air Toxics Policy modeling requirements.

2. Particulate Emissions

OAC rule 3745-17-07(A)(1) applies to this emissions unit

The SIP based limit (from 3745-17-11: Uncontrolled mass emission rate cannot be determined, therefore Table II does not apply. Per Table I, the calculated SIP allowable is:

\[ E = 4.10(P)^{0.67} \]

where P is the process weight rate falling within 0.05 tons/hr < P < 30 tons per hour

\[ P = 0.346 \text{ tons / hr} \]

\[ E = 2.01 \text{ lb/hr} \]

On an annual basis the uncontrolled PTE can be calculated using the SIP allowable hourly mass emissions rate

\[ (E * 8760 \text{ hours / year}) / (2000 \text{ lb/ton}) = 8.80 \text{ tons / year} \]

There are two (2) filtration systems associated with this air emissions source, both of which are integral to the process and are considered inherent physical restrictions. The fabric filter has an collection efficiency of 95% and HEPA filtration is 99.97% effective for particles 0.3 microns or greater. Incorporating the control efficiency of the integral control devices results in

\[ 2.01 \text{ lb / hr} * (1-0.95) * (1-0.9997) = 0.0000301 \text{ lbs / hr} \]

\[ 8.8 \text{ tons / year} * (1-0.95) * (1-0.9997) = 0.000132 \text{ tons / year} \]
3. Air Toxics

This air emissions unit triggers Ohio Air Toxics Policy because it emits > 1 ton / yr of ethanol. Ethanol has a TLV of 1000 ppm or 1883 mg / m$^3$. The maximum emission rate for ethanol is 69 lbs / hr, which assumes that all of the ethanol for the batch is added and evaporated within the first hour of the two-hour batch operation.

Pollutant: ethanol
TLV: 1883 mg / m$^3$
Max. Hourly Emission Rate = 69 lb / hr
Predicted 1-hour Max. Ground Level Concentration at the Fenceline (ug / m$^3$) = 785.0
Maximum Acceptable Ground-Level Concentration (MAGLC) (ug / m$^3$): 44,833.3

The modeled maximum ground level concentration does not exceed the MAGLC.

D. Conclusion

Similar permits for this facility have no controls for OC. Potential emissions are low and should not adversely affect ambient air quality.

This emission unit requires a Permit to Install Synthetic Minor to avoid becoming a Title V facility based on its maximum potential to emit for OC. If the operating mode changes (i.e. increase in batches processed per day) then further modifications to this permit may be necessary to avoid triggering Title V permitting requirements.
You are hereby notified that the Ohio Environmental Protection Agency has made a draft action recommending that the Director issue a Permit to Install for the air contaminant source(s) [emissions unit(s)] shown on the enclosed draft permit. This draft action is not an authorization to begin construction or modification of your emissions unit(s). The purpose of this draft is to solicit public comments on the proposed installation. A public notice concerning the draft permit will appear in the Ohio EPA Weekly Review and the newspaper in the county where the facility will be located. Public comments will be accepted by the field office within 30 days of the date of publication in the newspaper. Any comments you have on the draft permit should be directed to the appropriate field office within the comment period. A copy of your comments should also be mailed to Robert Hodanbosi, Division of Air Pollution Control, Ohio EPA, P.O. Box 1049, Columbus, OH, 43266-0149.

A Permit to Install may be issued in proposed or final form based on the draft action, any written public comments received within 30 days of the public notice, or record of a public meeting if one is held. You will be notified in writing of a scheduled public meeting. Upon issuance of a final Permit to Install a fee of $200 will be due. Please do not submit any payment now.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469. If you have any questions about this draft permit, please contact the field office where you submitted your application, or Mike Ahern, Field Operations & Permit Section at (614) 644-3631.

Sincerely,

Michael W. Ahern, Manager
Permit Issuance and Data Management Section
Division of Air Pollution Control
PUBLIC NOTICE
ISSUANCE OF DRAFT PERMIT TO INSTALL 01-12044 FOR AN AIR CONTAMINANT SOURCE FOR Boehringer Ingelheim Roxane, Inc.

On 8/24/2006 the Director of the Ohio Environmental Protection Agency issued a draft action of a Permit To Install an air contaminant source for Boehringer Ingelheim Roxane, Inc., located at 1809 Wilson Road, Columbus, Ohio.

Installation of the air contaminant source identified below may proceed upon final issuance of Permit To Install 01-12044:

Fluid bed/granulator dryer.

Comments concerning this draft action, or a request for a public meeting, must be sent in writing to the address identified below no later than thirty (30) days from the date this notice is published. All inquiries concerning this draft action may be directed to the contact identified below.

Isaac Robinson, Ohio EPA, Central District Office, 3232 Alum Creek Drive, Columbus, OH 43207-3417 [(614)728-3778]
DRAFT PERMIT TO INSTALL 01-12044

Application Number: 01-12044
Facility ID: 0125041763
Permit Fee: To be entered upon final issuance
Name of Facility: Boehringer Ingelheim Roxane, Inc.
Person to Contact: Mark Slaiman
Address: 1809 Wilson Rd
           Columbus, OH 43216

Location of proposed air contaminant source(s) [emissions unit(s)]:
1809 Wilson Road
Columbus, Ohio

Description of proposed emissions unit(s):
Fluid bed/granulator dryer.

The above named entity is hereby granted a Permit to Install for the above described emissions unit(s) pursuant to Chapter 3745-31 of the Ohio Administrative Code. Issuance of this permit does not constitute expressed or implied approval or agreement that, if constructed or modified in accordance with the plans included in the application, the above described emissions unit(s) of environmental pollutants will operate in compliance with applicable State and Federal laws and regulations, and does not constitute expressed or implied assurance that if constructed or modified in accordance with those plans and specifications, the above described emissions unit(s) of pollutants will be granted the necessary permits to operate (air) or NPDES permits as applicable.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director
A. Permit to Install General Terms and Conditions

1. Compliance Requirements

The emissions unit(s) identified in this Permit to Install shall remain in full compliance with all applicable State laws and regulations and the terms and conditions of this permit.

2. Reporting Requirements

The permittee shall submit required reports in the following manner:

a. Reports of any required monitoring and/or recordkeeping information shall be submitted to the appropriate Ohio EPA District Office or local air agency.

b. Except as otherwise may be provided in the terms and conditions for a specific emissions unit, quarterly written reports of (a) any deviations (excursions) from emission limitations, operational restrictions, and control device operating parameter limitations that have been detected by the testing, monitoring, and recordkeeping requirements specified in this permit, (b) the probable cause of such deviations, and (c) any corrective actions or preventive measures which have been or will be taken, shall be submitted to the appropriate Ohio EPA District Office or local air agency. If no deviations occurred during a calendar quarter, the permittee shall submit a quarterly report, which states that no deviations occurred during that quarter. The reports shall be submitted quarterly, i.e., by January 31, April 30, July 31, and October 31 of each year and shall cover the previous calendar quarters. (These quarterly reports shall exclude deviations resulting from malfunctions reported in accordance with OAC rule 3745-15-06.)

3. Records Retention Requirements

Each record of any monitoring data, testing data, and support information required pursuant to this permit shall be retained for a period of five years from the date the record was created. Support information shall include, but not be limited to, all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit. Such records may be maintained in computerized form.

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections,
conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. **Scheduled Maintenance/Malfunction Reporting**

Any scheduled maintenance of air pollution control equipment shall be performed in accordance with paragraph (A) of OAC rule 3745-15-06. The malfunction of any emissions units or any associated air pollution control system(s) shall be reported to the appropriate Ohio EPA District Office or local air agency in accordance with paragraph (B) of OAC rule 3745-15-06. Except as provided in that rule, any scheduled maintenance or malfunction necessitating the shutdown or bypassing of any air pollution control system(s) shall be accompanied by the shutdown of the emissions unit(s) that is (are) served by such control system(s).

6. **Permit Transfers**

Any transferee of this permit shall assume the responsibilities of the prior permit holder. The appropriate Ohio EPA District Office or local air agency must be notified in writing of any transfer of this permit.

7. **Air Pollution Nuisance**

The air contaminants emitted by the emissions units covered by this permit shall not cause a public nuisance, in violation of OAC rule 3745-15-07.

8. **Termination of Permit to Install**

This Permit to Install shall terminate within eighteen months of the effective date of the Permit to Install if the owner or operator has not undertaken a continuing program of installation or modification or has not entered into a binding contractual obligation to undertake and complete within a reasonable time a continuing program of installation or modification. This deadline may be extended by up to 12 months if application is made to the Director within a reasonable time before the termination date and the party shows good cause for any such extension.

9. **Construction of New Sources(s)**

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency.
Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

If the construction of the proposed emissions unit(s) has already begun or has been completed prior to the date the Director of the Environmental Protection Agency approves the permit application and plans, the approval does not constitute expressed or implied assurance that the proposed facility has been constructed in accordance with the approved plans. The action of beginning and/or completing construction prior to obtaining the Director's approval constitutes a violation of OAC rule 3745-31-02. Furthermore, issuance of the Permit to Install does not constitute an assurance that the proposed source will operate in compliance with all Ohio laws and regulations. Approval of the plans in any case is not to be construed as an approval of the facility as constructed and/or completed. Moreover, issuance of the Permit to Install is not to be construed as a waiver of any rights that the Ohio Environmental Protection Agency (or other persons) may have against the applicant for starting construction prior to the effective date of the permit. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed facilities cannot meet the requirements of this permit or cannot meet applicable standards.

10. Public Disclosure

The facility is hereby notified that this permit, and all agency records concerning the operation of this permitted source, are subject to public disclosure in accordance with OAC rule 3745-49-03.

11. Applicability

This Permit To Install is applicable only to the emissions unit(s) identified in the Permit To Install. Separate Permit To Install for the installation or modification of any other emissions unit(s) are required for any emissions unit for which a Permit To Install is required.

12. Best Available Technology

As specified in OAC Rule 3745-31-05, all new sources must employ Best Available Technology (BAT). Compliance with the terms and conditions of this permit will fulfill this requirement.

13. Source Operation and Operating Permit Requirements After Completion of Construction
This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within ninety (90) days after commencing operation of the emissions unit(s) covered by this permit.

14. Construction Compliance Certification

The applicant shall provide Ohio EPA with a written certification (see enclosed form) that the facility has been constructed in accordance with the Permit to Install application and the terms and conditions of the Permit to Install. The certification shall be provided to Ohio EPA upon completion of construction but prior to startup of the source.

15. Fees

The permittee shall pay fees to the Director of the Ohio EPA in accordance with ORC section 3745.11 and OAC Chapter 3745-78. The permittee shall pay all applicable Permit to Install fees within 30 days after the issuance of this Permit to Install.

B. Permit to Install Summary of Allowable Emissions

The following information summarizes the total allowable emissions, by pollutant, based on the individual allowable emissions of each air contaminant source identified in this permit.

SUMMARY (for informational purposes only)
TOTAL PERMIT TO INSTALL ALLOWABLE EMISSIONS

<table>
<thead>
<tr>
<th>Pollutant</th>
<th>Tons Per Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>OC</td>
<td>8.28</td>
</tr>
<tr>
<td>PM</td>
<td>&lt;10</td>
</tr>
</tbody>
</table>
PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

1. The specific operations(s), property, and/or equipment which constitute this emissions unit are listed in the following table along with the applicable rules and/or requirements and with the applicable emissions limitations and/or control measures. Emissions from this unit shall not exceed the listed limitations, and the listed control measures shall be specified in narrative form following the table.

<table>
<thead>
<tr>
<th>Operations, Property, and/or Equipment - (P017) - 600L Fluidized Bed / Granulator Dryer</th>
<th>Applicable Rules/Requirements</th>
<th>Applicable Emissions Limitations/Control Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>OAC rule 3745-35-07(B)(1) (synthetic minor to avoid Title V)</td>
<td>Organic Compound (OC) emissions shall not exceed 8.28 tons per year based upon a rolling 12-month summation of the monthly emissions. (see B.1 below).</td>
<td></td>
</tr>
<tr>
<td>OAC rule 3745-21-07(G)(9)</td>
<td>Exempt from the requirements of OAC rule 3745-21-07(G)(2) by using non-photochemically reactive materials. (see A.2.a below).</td>
<td></td>
</tr>
<tr>
<td>OAC rule 3745-31-02(A)</td>
<td>PE emissions from the stack shall be less than 10.0 tons per year (see A.2.b below).</td>
<td></td>
</tr>
<tr>
<td>OAC rule 3745-17-07(A)(1)</td>
<td>Visible particulate emissions from any stack shall not exceed 20 percent opacity as a six-minute average, except as specified by rule.</td>
<td></td>
</tr>
<tr>
<td>OAC rule 3745-17-11(B)</td>
<td>Particulate Emissions (PE) shall not exceed 2.01 pounds per hour based on Table I.</td>
<td></td>
</tr>
</tbody>
</table>

2. Additional Terms and Conditions

2.a The permittee shall not use any photochemically reactive materials as defined in OAC rule 3745-21-01(C)

2.b Permit to Install 01-12044 for this air contaminant source takes into account the following voluntary restrictions (including the use of any applicable air pollution control equipment) as proposed by the permittee for the purpose of avoiding Best Available Technology (BAT) requirements under OAC rule 3745-31-05(A)(3) for particulate emissions:

i. The emissions unit shall use a fabric filter with 95% efficiency and a HEPA (high-efficiency particulate air) filter with 99.97% efficiency in series. This control equipment is considered an inherent physical limitation since the filtration system is used to ensure that the company
can account for the pharmaceutical powder utilized in each batch, by weight.

B. Operational Restrictions

1. The maximum annual production rate for this emissions unit shall not exceed 240 batches, based upon a rolling, 12 month summation of the production rates.

To ensure enforceability during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall not exceed the production levels specified in the following table:

<table>
<thead>
<tr>
<th>Month</th>
<th>Maximum Allowable Cumulative Production</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>1-2</td>
<td>200</td>
</tr>
<tr>
<td>1-3</td>
<td>240</td>
</tr>
<tr>
<td>1-4</td>
<td>240</td>
</tr>
<tr>
<td>1-5</td>
<td>240</td>
</tr>
<tr>
<td>1-6</td>
<td>240</td>
</tr>
<tr>
<td>1-7</td>
<td>240</td>
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<tr>
<td>1-8</td>
<td>240</td>
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<tr>
<td>1-9</td>
<td>240</td>
</tr>
<tr>
<td>1-10</td>
<td>240</td>
</tr>
<tr>
<td>1-11</td>
<td>240</td>
</tr>
<tr>
<td>1-12</td>
<td>240</td>
</tr>
</tbody>
</table>

After the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, compliance with the annual production rate limitation shall be based upon a rolling, 12 month summation of the production rates.

2. The pressure drop across the fabric filter shall be maintained within the range of 2.0 and 10.0 inches of water while the emissions unit is in operation.

3. The pressure drop across the HEPA filter shall be maintained within the range of 0.50 and 3.0 inches of water while the emissions unit is in operation.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall maintain monthly records of the following information for this
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emissions unit:

a. the number of pounds of OC per batch;

b. whether the OC employed was photochemically reactive;

c. the number of batches per month;

d. the rolling, 12 month summation of the number of batches;

e. the rolling, 12 month summation of OC emissions (a \times d); and

f. beginning after the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the rolling, 12 month summation of the production rates.

Also, during the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, the permittee shall record the cumulative production rate for each calendar month.

2. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the baghouse while the emissions unit is in operation. The monitoring equipment shall be installed, calibrated, operated, and maintained in accordance with the manufacturer’s recommendations, instructions, and operating manual(s). The permittee shall record the pressure drop across the baghouse on a daily basis.

3. The permittee shall properly install, operate, and maintain equipment to monitor the pressure drop across the HEPA filter while the emissions unit is in operation. The monitoring equipment shall be installed, calibrated, operated, and maintained in accordance with the manufacturer’s recommendations, instructions, and operating manual(s). The permittee shall record the pressure drop across the baghouse on a monthly basis.

4. The permit to install for this emissions unit (P017) was evaluated based on the actual materials and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application. The Ohio EPA's "Review of New Sources of Air Toxic Emissions" policy ("Air Toxic Policy") was applied to this emissions unit for each toxic pollutant, using data from the permit to install application (01-12044), and modeling was performed for the toxic pollutant emitted at over a ton per year using the SCREEN 3.0 model or other Ohio EPA approved model.
predicted 1-hour maximum ground-level concentration result from the use of the SCREEN 3.0 (or other approved) model, was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC), calculated as required in Engineering Guide #70. The following summarizes the results of the modeling for the "worst case" pollutant:

Pollutant: Ethanol  
TLV (mg/m³): 1883  
Maximum Hourly Emission Rate (lbs/hr): 69  
Predicted 1-Hour Maximum Ground-Level Concentration (ug/m³): 785.0  
MAGLC (ug/m³): 44833.3

5. Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be satisfied. If, upon evaluation, the permittee determines that the "Air Toxic Policy" will not be satisfied, the permittee will not make the change. Changes that can affect the parameters used in applying the "Air Toxic Policy" include the following:

a. changes in the composition of the materials used or the use of new materials, that would result in the emission of a compound or chemical with a lower Threshold Limit Value (TLV) than the lowest TLV previously modeled, as documented in the most current version of the American Conference of Governmental Industrial Hygienists' (ACGIH’s) handbook entitled "TLVs and BEIs" ("Threshold Limit Values for Chemical Substances and Physical Agents, Biological Exposure Indices");

b. changes in the composition of the materials, or use of new materials, that would result in an increase in emissions of any pollutant with a listed TLV that was proposed in the application and modeled; and

c. physical changes to the emissions unit or its exhaust parameters (e.g., increased/ decreased exhaust flow, changes in stack height, changes in stack diameter, etc.).

6. If the permittee determines that the "Air Toxic Policy" will be satisfied for the above changes, the Ohio EPA will not consider the change(s) to be a "modification" under OAC rule 3745-31-01 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis
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level in OAC rule 3745-15-05. If the change(s) meet(s) the definition of a "modification" under other provisions of the rule, then the permittee shall obtain a final permit to install prior to the change.

The permittee shall collect, record, and retain the following information when it conducts evaluations to determine that the changed emissions unit will still satisfy the "Air Toxic Policy":

a. a description of the parameters changed (composition of materials, new pollutants emitted, change in stack/exhaust parameters, etc.);

b. documentation of the evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy"; and

c. where computer modeling is performed, a copy of the resulting computer model runs that show the results of the application of the "Air Toxic Policy" for the change.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports that identify all exceedances of the rolling, 12 month production rate limitation; and for the first 12 calendar months of operation or the first 12 calendar months following the issuance of this permit, all exceedances of the maximum allowable cumulative production rate levels.

2. The permittee shall submit quarterly pressure drop deviation (excursion) reports that identify that all periods of time during which the pressure drop across the baghouse did not comply with the allowable range specified above.

3. The permittee shall submit quarterly pressure drop deviation (excursion) reports that identify all periods of time during which the pressure drop across the HEPA did not comply with the allowable range specified above.

4. These quarterly deviation (excursion) reports shall be submitted in accordance with the reporting requirements specified in Part 1 - General Terms and Conditions, Section A of this permit.

5. The permittee shall submit deviation (excursion) reports that identify all periods of time when a photochemically reactive material was employed in this emissions unit. These reports shall be submitted within 30 days after the occurrence.
E. Testing Requirements

1. Compliance with the emission limitations in Section A.I of these terms and conditions shall be determined in accordance with the following methods:

   a. Emission Limitation:

      OC emissions shall not exceed 8.28 tons per year based upon a rolling 12-month summation of the monthly emissions.

      Applicable Compliance Method:

      Compliance shall be demonstrated by through record keeping as required in section C.e. above.

   c. Emission Limitation:

      Particulate Emissions (PE) shall not exceed 2.01 pounds per hour based on Table I.

      Applicable Compliance Method:

      This emission limitation is established pursuant to the requirement specified in OAC rule 3745-17-11(A). Per Table I, the calculated State Implementation Plan (SIP) allowable is:

      \[ E = 4.10(P)^{0.67} \]

      Where:

      P is the process weight rate falling within 0.05 ton/hour < P < 30 tons per hour.

      \[ P = 0.346 \text{ ton/hour}. \]

      \[ E = 2.01 \text{ lbs/hour}. \]

      Taking into account the efficiency of the intrinsic control devices (95% for the fabric filter and 99.97% for the HEPA filter):

      \[ 2.01 \text{ lbs/hour} \times (1-0.95) \times (1-0.9997) = 0.0000301 \text{ lb/hour}. \]
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If required, compliance shall be demonstrated by emission stack test employing methods 1-5 of 40 CFR Part 60, Appendix A.

d. Emission Limitation:

Visible particulate emissions from any stack shall not exceed 20 percent opacity as a six-minute average, except as specified by rule.

Applicable Compliance Method:

If required, compliance shall be determined through visible emission observations performed in accordance with 40 CFR Part 60, Appendix A, Method 9 and the procedures specified in OAC rule 3745-17-03(B)(1).

F. Miscellaneous Requirements

None