Ohio Environmental Protection Agency

Ted Strickland, Governor
Lee Fisher, Lt. Governor
Chris Korleski, Director

Certified Mail

7/27/2010

No	TOXIC REVIEW
No	PSD
No	SYNTHETIC MINOR TO AVOID MAJOR NSR
No	CEMS
No	MACT
No	NSPS
No	NESHAPS
No	NETTING
No	MAJOR NON-ATTAINMENT
No	MODELING SUBMITTED
Yes	SYNTHETIC MINOR TO AVOID TITLE V
Yes	FEDERALLY ENFORCABLE PTIO (FEPTIO)

Mr. Dane Marsee
EURAND AMERICA INC
845 CENTER DR.
VANDALIA, OH 45377

RE: FINAL AIR POLLUTION PERMIT-TO-INSTALL AND OPERATE
Facility ID: 0857171794
Permit Number: P0106407
Permit Type: Renewal
County: Montgomery

Dear Permit Holder:

Enclosed please find a final Air Pollution Permit-to-Install and Operate (PTIO) which will allow you to install, modify, and/or operate the described emissions unit(s) in the manner indicated in the permit. Because this permit contains conditions and restrictions, please read it very carefully. Please complete a survey at www.epa.ohio.gov/dapc/permitsurvey.aspx and give us feedback on your permitting experience. We value your opinion.

The issuance of this PTI is a final action of the Director and may be appealed to the Environmental Review Appeals Commission pursuant to Section 3745.04 of the Ohio Revised Code. The appeal must be in writing and set forth the action complained of and the grounds upon which the appeal is based. The appeal must be filed with the Commission within thirty (30) days after notice of the Director's action. The appeal must be accompanied by a filing fee of $70.00, made payable to "Ohio Treasurer Kevin Boyce," which the Commission, in its discretion, may reduce if by affidavit you demonstrate that payment of the full amount of the fee would cause extreme hardship. Notice of the filing of the appeal shall be filed with the Director within three (3) days of filing with the Commission. Ohio EPA requests that a copy of the appeal be served upon the Ohio Attorney General's Office, Environmental Enforcement Section. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
309 South Fourth Street, Room 222
Columbus, OH 43215

If you have any questions, please contact Regional Air Pollution Control Agency at (937)225-4435 or the Office of Compliance Assistance and Pollution Prevention at (614) 644-3469. This permit can be accessed electronically on the DAPC Web page, www.epa.ohio.gov/dapc, by clicking the "Issued Air Pollution Control Permits" link.

Sincerely,

Michael W. Ahern

Michael W. Ahern, Manager
Permit Issuance and Data Management Section, DAPC

Cc: RAPCA

50 West Town Street, Suite 700
P.O. Box 1049
Columbus, OH 43216-1049

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Ohio | Environmental Protection Agency

FINAL

Division of Air Pollution Control
Permit-to-Install and Operate
for
EURAND AMERICA INC

Facility ID: 0857171794
Permit Number: P0106407
Permit Type: Renewal
Issued: 7/27/2010
Effective: 7/27/2010
Expiration: 7/27/2015

Ohio Environmental Protection Agency

Division of Air Pollution Control
Permit-to-Install and Operate
for
EURAND AMERICA INC

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Authorization

Facility ID: 0857171794
Application Number(s): A0039308
Permit Number: P0106407
Permit Description: Renewal FEPTIO
Permit Type: Renewal
Permit Fee: $0.00
Issue Date: 7/27/2010
Effective Date: 7/27/2010
Expiration Date: 7/27/2015
Permit Evaluation Report (PER) Annual Date: Oct 1 - Sept 30, Due Nov 15

This document constitutes issuance to:

EURAND AMERICA INC
845 CENTER DR.
VANDALIA, OH 45377

of a Permit-to-Install and Operate for the emissions unit(s) identified on the following page.

Ohio EPA District Office or local air agency responsible for processing and administering your permit:

Regional Air Pollution Control Agency
117 South Main Street
Dayton, OH 45422-1280
(937)225-4435

The above named entity is hereby granted this Permit-to-Install and Operate for the air contaminant source(s) (emissions unit(s)) listed in this section 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 described emissions unit(s) will operate in compliance with applicable State and federal laws and regulations.

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Chris Korleski
Director

Authorization (continued)

Permit Number: P0106407
Permit Description: Renewal FEPTIO

Permits for the following Emissions Unit(s) or groups of Emissions Units are in this document as indicated below:

Emissions Unit ID:	**P012**
Company Equipment ID:	Pharmaceuticals Spray Coating System
Superseded Permit Number:	08-04386
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P017**
Company Equipment ID:	GPCG 120 Fluid Bed Coater
Superseded Permit Number:	08-04386
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P019**
Company Equipment ID:	Gruenberg Tray Oven
Superseded Permit Number:	08-04572
General Permit Category and Type:	Not Applicable

Group Name: Glatt Fluid Bed Coaters

Emissions Unit ID:	**P008**
Company Equipment ID:	Glatt Fluid Bed Coater - GPCG-5
Superseded Permit Number:	08-04603
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P014**
Company Equipment ID:	R&D Pan Coater
Superseded Permit Number:	08-04386
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P015**
Company Equipment ID:	R&D Glatt Fluid Bed Coater GPCG-3
Superseded Permit Number:	08-04386
General Permit Category and Type:	Not Applicable
Emissions Unit ID:	**P020**
Company Equipment ID:	R&D Glatt Fluid Bed Coater GPCG-3 (new)
Superseded Permit Number:	08-04680
General Permit Category and Type:	Not Applicable

A. Standard Terms and Conditions

1. What does this permit-to-install and operate ("PTIO") allow me to do?

This permit allows you to install and operate the emissions unit(s) identified in this PTIO. You must install and operate the unit(s) in accordance with the application you submitted and all the terms and conditions contained in this PTIO, including emission limits and those terms that ensure compliance with the emission limits (for example, operating, recordkeeping and monitoring requirements).

2. Who is responsible for complying with this permit?

The person identified on the "Authorization" page, above, is responsible for complying with this permit until the permit is revoked, terminated, or transferred. "Person" means a person, firm, corporation, association, or partnership. The words "you," "your," or "permittee" refer to the "person" identified on the "Authorization" page above.
The permit applies only to the emissions unit(s) identified in the permit. If you install or modify any other equipment that requires an air permit, you must apply for an additional PTIO(s) for these sources.

3. What records must I keep under this permit?

You must keep all records required by this permit, including monitoring data, test results, strip-chart recordings, calibration data, maintenance records, and any other record required by this permit for five years from the date the record was created. You can keep these records electronically, provided they can be made available to Ohio EPA during an inspection at the facility. Failure to make requested records available to Ohio EPA upon request is a violation of this permit requirement.

4. What are my permit fees and when do I pay them?

There are two fees associated with permitted air contaminant sources in Ohio:

- PTIO fee. This one-time fee is based on a fee schedule in accordance with Ohio Revised Code (ORC) section 3745.11, or based on a time and materials charge for permit application review and permit processing if required by the Director.

  You will be sent an invoice for this fee after you receive this PTIO and payment is due within 30 days of the invoice date. You are required to pay the fee for this PTIO even if you do not install or modify your operations as authorized by this permit.

- Annual emissions fee. Ohio EPA will assess a separate fee based on the total annual emissions from your facility. You self-report your emissions in accordance with Ohio Administrative Code (OAC) Chapter 3745-78. This fee assessed is based on a fee schedule in ORC section 3745.11 and funds Ohio EPA's permit compliance oversight activities. Unless otherwise specified, facilities subject to one or more synthetic minor restrictions must use Ohio EPA's "Air Services" to submit annual emissions associated with this permit requirement. Ohio EPA will notify you when it is time to report your emissions and to pay your annual emission fees.

5. When does my PTIO expire, and when do I need to submit my renewal application?

This permit expires on the date identified at the beginning of this permit document (see "Authorization" page above) and you must submit a renewal application to renew the permit. Ohio EPA will send a renewal notice to you approximately six months prior to the expiration date of this permit. However, it is very important that you submit a complete renewal permit application (postmarked prior to expiration of

this permit) even if you do not receive the renewal notice.
If a complete renewal application is submitted before the expiration date, Ohio EPA considers this a timely application for purposes of ORC section 119.06, and you are authorized to continue operating the emissions unit(s) covered by this permit beyond the expiration date of this permit until final action is taken by Ohio EPA on the renewal application.

6. What happens to this permit if my project is delayed or I do not install or modify my source?

This PTIO expires 18 months after the issue date identified on the "Authorization" page above unless otherwise specified if you have not (1) started constructing the new or modified emission sources identified in this permit, or (2) entered into a binding contract to undertake such construction. This deadline can be extended by up to 12 months, provided you apply to Ohio EPA for this extension within a reasonable time before the 18-month period has ended and you can show good cause for any such extension.

7. What reports must I submit under this permit?

An annual permit evaluation report (PER) is required in addition to any malfunction reporting required by OAC rule 3745-15-06 or other specific rule-based reporting requirement identified in this permit. Your PER due date is identified in the Authorization section of this permit.

8. If I am required to obtain a Title V operating permit in the future, what happens to the operating provisions and PER obligations under this permit?

If you are required to obtain a Title V permit under OAC Chapter 3745-77 in the future, the permit-to-operate portion of this permit will be superseded by the issued Title V permit. From the effective date of the Title V permit forward, this PTIO will effectively become a PTI (permit-to-install) in accordance with OAC rule 3745-31-02(B). The following terms and conditions will no longer be applicable after issuance of the Title V permit: Section B, Term 1.b) and Section C, for each emissions unit, Term a)(2).
The PER requirements in this permit remain effective until the date the Title V permit is issued and is effective, and cease to apply after the effective date of the Title V permit. The final PER obligation will cover operations up to the effective date of the Title V permit and must be submitted on or before the submission deadline identified in this permit on the last day prior to the effective date of the Title V permit.

9. What are my obligations when I perform scheduled maintenance on air pollution control equipment?

You must perform scheduled maintenance of air pollution control equipment in accordance with OAC rule 3745-15-06(A). If scheduled maintenance requires shutting down or bypassing any air pollution control equipment, you must also shut down the emissions unit(s) served by the air pollution control equipment during maintenance, unless the conditions of OAC rule 3745-15-06(A)(3) are met. Any emissions that exceed permitted amount(s) under this permit (unless specifically exempted by rule) must be reported as deviations in the annual permit evaluation report (PER), including nonexempt excess emissions that occur during approved scheduled maintenance.

10. Do I have to report malfunctions of emissions units or air pollution control equipment? If so, how must I report?

If you have a reportable malfunction of any emissions unit(s) or any associated air pollution control system, you must report this to the Regional Air Pollution Control Agency in accordance with OAC rule 3745-15-06(B). Malfunctions that must be reported are those that result in emissions that exceed permitted emission levels. It is your responsibility to evaluate control equipment breakdowns and operational upsets to determine if a reportable malfunction has occurred.
If you have a malfunction, but determine that it is not a reportable malfunction under OAC rule 3745-15-06(B), it is recommended that you maintain records associated with control equipment breakdown or process upsets. Although it is not a requirement of this permit, Ohio EPA recommends that you maintain records for non-reportable malfunctions.

11. Can Ohio EPA or my local air agency inspect the facility where the emission unit(s) is/are located?

Yes. Under Ohio law, the Director or his authorized representative may inspect the facility, conduct tests, examine records or reports to determine compliance with air pollution laws and regulations and the terms and conditions of this permit. You must provide, within a reasonable time, any information Ohio EPA requests either verbally or in writing.

12. What happens if one or more emissions units operated under this permit is/are shut down permanently?

Ohio EPA can terminate the permit terms associated with any permanently shut down emissions unit. "Shut down" means the emissions unit has been physically removed from service or has been altered in such a way that it can no longer operate without a subsequent "modification" or "installation" as defined in OAC Chapter 3745-31.
You should notify Ohio EPA of any emissions unit that is permanently shut down by submitting[1] a certification that identifies the date on which the emissions unit was permanently shut down. The certification must be submitted by an authorized official from the facility. You cannot continue to operate an emissions unit once the certification has been submitted to Ohio EPA by the authorized official.
You must comply with all recordkeeping and reporting for any permanently shut down emissions unit in accordance with the provisions of the permit, regulations or laws that were enforceable during the period of operation, such as the requirement to submit a PER, air fee emission report, or malfunction report. You must also keep all records relating to any permanently shutdown emissions unit, generated while the emissions unit was in operation, for at least five years from the date the record was generated.
Again, you cannot resume operation of any emissions unit certified by the authorized official as being permanently shut down without first applying for and obtaining a permit pursuant to OAC Chapter 3745-31.

13. Can I transfer this permit to a new owner or operator?

You can transfer this permit to a new owner or operator. If you transfer the permit, you must follow the procedures in OAC Chapter 3745-31, including notifying Ohio EPA or the local air agency of the

[1] Permittees that use Ohio EPA's "Air Services" can mark the affected emissions unit(s) as "permanently shutdown" in the facility profile along with the date the emissions unit(s) was permanently removed and/or disabled. Submitting the facility profile update will constitute notifying of the permanent shutdown of the affected emissions unit(s).

change in ownership or operator. Any transferee of this permit must assume the responsibilities of the transferor permit holder.

14. Does compliance with this permit constitute compliance with OAC rule 3745-15-07, "air pollution nuisance"?

This permit and OAC rule 3745-15-07 prohibit operation of the air contaminant source(s) regulated under this permit in a manner that causes a nuisance. Ohio EPA can require additional controls or modification of the requirements of this permit through enforcement orders or judicial enforcement action if, upon investigation, Ohio EPA determines existing operations are causing a nuisance.

15. What happens if a portion of this permit is determined to be invalid?

If a portion of this permit is determined to be invalid, the remainder of the terms and conditions remain valid and enforceable. The exception is where the enforceability of terms and conditions are dependent on the term or condition that was declared invalid.

B. Facility-Wide Terms and Conditions

1. This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

   a) For the purpose of a permit-to-install document, the facility-wide terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

      (1) None.

   b) For the purpose of a permit-to-operate document, the facility-wide terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

      (1) None.

C. Emissions Unit Terms and Conditions

1. P012, Pharmaceuticals Spray Coating System

Operations, Property and/or Equipment Description:

Pharmaceuticals processing system controlled by a catalytic oxidizer

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. d)(7) and d)(8).

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3)	Organic Compound (OC) emissions from this emissions unit shall not exceed 5.0 lbs/hour. See b)(2)d. for emission control measures.
b.	OAC rule 3754-31-05(D) (synthetic minor to avoid Title V)	OC emissions from this emissions unit shall not exceed 16.8 TPY, as a rolling, 12 -month summation. See b)(2)d. for emission control measures.
c.	OAC rule 3745-21-07(M)(1) and (M)(2).	The control requirement specified by this rule is less stringent than the control requirement established pursuant to OAC rule 3745-31-05(A)(3).
d.	OAC rule 3745-21-07(G)(2) effective 6/15/1999	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		rule 3745-31-05(A)(3). See b)(2)e.

(2) Additional Terms and Conditions

a. The hourly OC emissions limit was established to reflect the controlled potential to emit for this emissions unit. Therefore, it is not necessary to develop record keeping and/or reporting requirements to ensure compliance with this short term emissions limitation.

b. The emissions of OC from this emissions unit shall not exceed 16.8 tons per year, based upon a rolling, 12-month summation of the monthly emissions.

c. All of the OC emissions from this emissions unit shall be vented to a catalytic oxidizer that shall meet the operational, monitoring, and record keeping requirements of this permit, when the emissions unit is in operation.

d. The OC emissions from emissions unit P012 shall be controlled through the application of a HEPA filter for particulate removal and application of the CSM catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency [The CSM catalytic oxidizer system is a common OC control device for emissions units P012 and P017].

e. On February 18, 2008, OAC rule 3745-21-07 was partially revised; therefore, the 21-07(G)(2) rule that was in effect prior to this date is no longer part of the State regulations. On April 4, 2008, the rule revision was submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP); however, until the U.S. EPA approves the revision to OAC rule 3745-21-07, the requirement to comply with the previous 21-07(G)(2) rule provisions still exists as part of the federally-approved SIP for Ohio. The following terms and conditions shall become void after U.S. EPA approves the rule revision: b)(1)d.

c) Operational Restrictions

(1) The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

(2) The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream and downstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees

Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

(2) The permittee shall collect and record the following information each day:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

(3) The permittee shall collect and record the following information each month:

a. The number of batches.

b. The number of gallons of each organic compound solvent material employed in each batch.

c. The density of each organic compound solvent material employed, in pounds per gallon.

d. The pounds of organic compound solvent material employed in each batch, i.e., d)(3)b. X d)(3)c.

e. The monthly before-control OC emission rate for all organic compound solvent materials employed, in pounds per month, i.e., the summation of d)(3)d. for all batches made in P012 for the month.

f. The monthly controlled OC emission rate for all organic compound solvent materials, in pounds per month, i.e., the value in d)(3)e. multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.

g. The rolling 12-month emissions of OC, i.e., the summation of d)(3)f. for the previous 12-month period divided by 2000 lbs/ton.

(4) The permittee shall perform a preventive maintenance inspection of the CSM catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in CSM's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and record equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in f)(2).

(5) Whenever the monitored average temperature of the exhaust gases immediately before the catalyst bed deviates from the range or limit established in accordance with this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. the date and time the deviation began;

b. the magnitude of the deviation at that time;

c. the date the investigation was conducted;

d. the name(s) of the personnel who conducted the investigation; and

e. the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range(s)/limit(s) specified in this permit, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

a. a description of the corrective action;

b. the date corrective action was completed;

c. the date and time the deviation ended;

d. the total period of time (in minutes) during which there was a deviation;

e. the temperature of the exhaust gases immediately before the catalyst bed immediately after the corrective action was implemented; and

f. the name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The temperature ranges are effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA District Office or local air agency. The permittee may request revisions to the permitted temperature range(s) based upon information obtained during future performance tests that demonstrate compliance with the allowable emission rate(s) of the controlled pollutant(s). In addition, approved revisions to the temperature range(s) will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

(6) The permittee shall calculate and maintain monthly records of the OC emissions and the rolling 12-month emissions of OC.

(7) The permit to install for this emissions unit (P012) was evaluated based on the actual materials (typically coatings and cleanup 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 for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Isopropyl Alcohol

TLV (mg/m3): 983

Maximum Hourly Emission Rate (lbs/hr): 5.0

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 520

MAGLC (ug/m3): 23,406

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 still 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 (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

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.).

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(VV)(1)(a)(ii), and a modification of the existing permit to install will not

be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

(8) 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 its 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.

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation (excursion) reports that identify:

a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:

i. all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance;

ii. all exceedances of the rolling, 12-month emission limitation for OC;

iii. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer.

b. the probable cause of each deviation (excursion);

c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and

d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.

The quarterly reports shall be submitted, electronically through Ohio EPA Air Services, each year by January 31 (covering October to December), April 30 (covering January to

March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate District Office or local air agency).

(2) The permittee shall identify in the annual permit evaluation report the following information concerning the operations of the catalytic oxidizer during the 12-month reporting period for this/these emissions unit(s):

a. each period of time (start time and date, and end time and date) when the average temperature of the exhaust gases immediately before the catalyst bed was outside of the acceptable ranges;

b. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer;

c. each incident of deviation described in e)(2)a. or e)(2)b. where a prompt investigation was not conducted;

d. each incident of deviation described in e)(2)a. or e)(2)b. where prompt corrective action, that would bring the emissions unit(s) into compliance and/or the temperature of the exhaust gases immediately before the catalyst bed into compliance with the acceptable range(s), was determined to be necessary and was not taken;

e. each incident of deviation described in e)(2)a. or e)(2)b. where proper records were not maintained for the investigation and/or the corrective action(s), as identified in the monitoring and record keeping requirements of this permit; and

(3) Annual Permit Evaluation Report (PER) forms will be mailed to the permittee at the end of the reporting period specified in the Authorization section of this permit. The permittee shall submit the PER in the form and manner provided by the director by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

(4) The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the CSM catalytic oxidizer system required in f)(2) of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

f) Testing Requirements

(1) Compliance with the emission limitation(s) in b)(1) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitation

OC emissions from this emissions unit shall not exceed 5.0 lbs/hr.

Applicable Compliance Method

Compliance shall be determined by performance testing as specified in f)(3).

b. Emission Limitation

OC emissions from this emissions unit shall not exceed 16.8 TPY OC, based on a rolling, 12-month summation.

Applicable Compliance Method

Compliance shall be determined by the recordkeeping as specified in d)(3).

(2) The permittee shall conduct, or have conducted, on an annual basis (every 10 to 18 months), either catalyst activity test, emissions testing, or catalyst replacement on the (Megtec/CSM) catalytic oxidizer system in accordance with the (Megtec/CSM) "Catalyst Sampling and Catalyst Testing" protocol. An Intent to Test notification shall not be required for testing of catalyst activity and catalyst replacement.

(3) The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

a. The emission testing shall be conducted within 12 months after issuance of this permit.

b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for OC.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):

Method 18 of 40 CFR Part 60, Appendix A, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds.

Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 of the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95")

d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

e. Not later than 60 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the appropriate Ohio EPA District Office or local air agency. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Ohio EPA District Office's or local air agency's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA District Office or local air agency shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

g) Miscellaneous Requirements

(1) The terms and conditions of this permit to install and operate shall supersede all terms and conditions for emissions unit P012 in PTI 08-04386 issued December 29, 2006 and represent an Administrative Modification to change recordkeeping requirements for emissions unit P012 from 365-day rolling OC records to 12-month rolling OC records.

2. P017, GPCG 120 Fluid Bed Coater

Operations, Property and/or Equipment Description:

Glatt 120 pharmaceutical spray coater controlled by a catalytic oxidizer

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. d)(8) and d)(9).

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3)	Organic compound (OC) emissions from this emissions unit shall not exceed 5.56 lbs/hr. See b)(2)d. for emission control measures.
b.	OAC rule 3754-31-05(D) (Synthetic Minor to avoid Title V)	Organic compound (OC) emissions from emissions unit shall not exceed 19.5 TPY as a rolling 12-month summation See b)(2)d. for emission control measures.
c.	OAC rule 3745-21-07(M)(1) and (M)(2).	The control requirement specified by this rule is less stringent than the control requirement established pursuant to OAC rule 3745-31-05(A)(3).
d.	OAC rule 3745-21-07(G)(2) effective 6/15/1999	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		rule 3745-31-05(A)(3). See b)(2)(e).

(2) Additional Terms and Conditions

a. The hourly OC emissions limit was established to reflect the controlled potential to emit for this emissions unit. Therefore, it is not necessary to develop record keeping and/or reporting requirements to ensure compliance with this short term emissions limitation.

b. The emissions of OC from this emissions unit shall not exceed 19.5 tons per year, based upon a rolling, 12-month summation of the monthly emissions.

c. All of the OC emissions from this emissions unit shall be vented to the/a catalytic oxidizer that shall meet the operational, monitoring, and record keeping requirements of this permit, when the emissions unit is in operation.

d. The OC emissions from this emissions unit shall be controlled through the application of either the Megtec catalytic oxidizer system or the CSM catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [The Megtec catalytic oxidizer system is a common OC control device for emissions units P001, P008, P014, P015, P017, P019, and P020. The CSM catalytic oxidizer system is a common OC control device for emissions units P012 and P017.].

e. On February 18, 2008, OAC rule 3745-21-07 was partially revised; therefore, the 21-07(G)(2) rule that was in effect prior to this date is no longer part of the State regulations. On April 4, 2008, the rule revision was submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP); however, until the U.S. EPA approves the revision to OAC rule 3745-21-07, the requirement to comply with the previous 21-07(G)(2) rule provisions still exists as part of the federally-approved SIP for Ohio. The following terms and conditions shall become void after U.S. EPA approves the rule revision: b)(1)d.

c) Operational Restrictions

(1) When emissions unit P017 is venting to the CSM catalytic oxidizer the following shall apply:

a. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

(2) When emissions unit P017 is venting to the Megtec catalytic oxidizer the following shall apply:

a. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

d) Monitoring and/or Recordkeeping Requirements

(1) For each product batch run on this emissions unit, the permittee shall maintain a record of which catalytic oxidizer system the emission unit is vented and the date.

(2) The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream and downstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

(3) The permittee shall collect and record the following information each day when emissions unit P017 is venting to the CSM catalytic oxidizer:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

(4) The permittee shall collect and record the following information each day when emissions unit P017 is venting to the Megtec catalytic oxidizer:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

(5) The permittee shall collect and record the following information each month:

a. The number of batches.

b. The number of gallons of each organic compound solvent material employed in each batch.

c. The density of each organic compound solvent material employed, in pounds per gallon.

d. The pounds of organic compound solvent material employed in each batch, i.e., d)(5)b. X d)(5)c.

e. The monthly before-control OC emission rate for all organic compound solvent materials employed, in pounds per month, i.e., the summation of d)(5)d. for all batches made in P017 for the month.

f. The monthly controlled OC emission rate for all organic compound solvent materials, in pounds per month, i.e., the value in d)(5)e. multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.

g. The rolling 12-month emissions of OC, i.e., the summation of d)(5)f. for the previous 12-month period divided by 2000 lbs/ton.

(6) The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and record equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in f)(2).

(7) The permittee shall perform a preventive maintenance inspection of the CSM catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and record equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in f)(2).

(8) The permit to install for this emissions unit (P017) was evaluated based on the actual materials (typically coatings and cleanup 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 for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Isopropyl Alcohol

TLV (mg/m3): 983

Maximum Hourly Emission Rate (lbs/hr): 5.56

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 1240

MAGLC (ug/m3): 23,406

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 still 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 (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

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.).

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(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

(9) 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 its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy".

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.

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation (excursion) reports that identify:

a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:

i. all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance;

ii. all exceedances of the rolling, 12-month emission limitation for OC;

iii. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to a catalytic oxidizer.

b. the probable cause of each deviation (excursion);

c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and

d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.

The quarterly reports shall be submitted, electronically through Ohio EPA Air Services, each year by January 31 (covering October to December), April 30 (covering January to March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate District Office or local air agency).

(2) The permittee shall identify in the annual permit evaluation report the following information concerning the operations of the catalytic oxidizer during the 12-month reporting period for this/these emissions unit(s):

a. each period of time (start time and date, and end time and date) when the average temperature of the exhaust gases immediately before the catalyst bed was outside of the acceptable ranges;

b. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer;

c. each incident of deviation described in e)(2)a. or e)(2)b. where a prompt investigation was not conducted;

d. each incident of deviation described in e)(2)a. or e)(2)b. where prompt corrective action, that would bring the emissions unit(s) into compliance and/or the temperature of the exhaust gases immediately before the catalyst bed into compliance with the acceptable range(s), was determined to be necessary and was not taken;

e. each incident of deviation described in e)(2)a. or e)(2)b. where proper records were not maintained for the investigation and/or the corrective action(s), as identified in the monitoring and record keeping requirements of this permit; and

(3) Annual Permit Evaluation Report (PER) forms will be mailed to the permittee at the end of the reporting period specified in the Authorization section of this permit. The permittee shall submit the PER in the form and manner provided by the director by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

(4) The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the CSM catalytic oxidizer system and the Megtec catalytic oxidizer system required in f)(2) of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

f) Testing Requirements

(1) Compliance with the emission limitation(s) in b)(1) of these terms and conditions shall be determined in accordance with the following methods:

a. <u>Emission Limitation</u>

OC emissions from this emissions unit shall not exceed 5.56 lbs/hr.

Applicable Compliance Method

Compliance shall be determined by performance testing as specified in f)(3).

b. Emission Limitation

OC emissions from this emissions unit shall not exceed 19.5 TPY OC, based on a rolling, 12-month summation.

Applicable Compliance Method

Compliance shall be determined by the recordkeeping as specified in d)(5).

(2) The permittee shall conduct, or have conducted, on an annual basis (every 10 to 18 months), either catalyst activity test, emissions testing, or catalyst replacement on the (Megtec/CSM) catalytic oxidizer system in accordance with the (Megtec/CSM) "Catalyst Sampling and Catalyst Testing" protocol. An Intent to Test notification shall not be required for testing of catalyst activity and catalyst replacement.

(3) The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

a. The emission testing shall be conducted 6 months prior to permit renewal.

b. The emission testing shall be conducted to demonstrate compliance with the demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for OC.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):

Method 18 of 40 CFR Part 60, Appendix A, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds.

Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 of the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95")

d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

e. Not later than 60 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the appropriate Ohio EPA District Office or local air agency. The "Intent to Test" notification shall describe in detail the

proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Ohio EPA District Office's or local air agency's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA District Office or local air agency shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

g) Miscellaneous Requirements

(1) The terms and conditions of this permit to install and operate shall supersede all terms and conditions for emissions unit P017 in PTI 08-04386 issued December 29, 2006 and represent an Administrative Modification to change recordkeeping requirements for emissions unit P017 from 365-day rolling OC records to 12-month rolling OC records.

3. P019, Gruenberg Tray Oven

Operations, Property and/or Equipment Description:

Gruenberg Tray Oven controlled by catalytic oxidizer

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. d)(7) and d)(8).

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3)	Organic compound (OC) emissions from this emissions unit shall not exceed 0.41 lbs/hr. See b)(2)d. for emission control measures.
b.	OAC rule 3754-31-05(D) (Synthetic Minor to avoid Title V)	Organic compound (OC) emissions from emissions unit shall not exceed 1.34 TPY as a rolling 12-month summation See b)(2)d. for emission control measures.
c.	OAC rule 3745-21-07(M)(1) and (M)(2).	The control requirement specified by this rule is less stringent than the control requirement established pursuant to OAC rule 3745-31-05(A)(3).
d.	OAC rule 3745-21-07(G)(2) effective 6/15/1999	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
		rule 3745-31-05(A)(3). See b)(2)(e).

(2) Additional Terms and Conditions

a. The hourly OC emissions limit was established to reflect the controlled potential to emit for this emissions unit. Therefore, it is not necessary to develop record keeping and/or reporting requirements to ensure compliance with this short term emissions limitation.

b. The emissions of OC from this emissions unit shall not exceed 1.34 tons per year, based upon a rolling, 12-month summation of the monthly emissions.

c. All of the OC emissions from this emissions unit shall be vented to the/a catalytic oxidizer that shall meet the operational, monitoring, and record keeping requirements of this permit, when the emissions unit is in operation.

d. The OC emissions from this emissions unit shall be controlled through the application of a catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [The Megtec catalytic oxidizer system is a common OC control device for emissions units P001, P008, P014, P015, P017, P019, and P020.].

e. On February 18, 2008, OAC rule 3745-21-07 was partially revised; therefore, the 21-07(G)(2) rule that was in effect prior to this date is no longer part of the State regulations. On April 4, 2008, the rule revision was submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP); however, until the U.S. EPA approves the revision to OAC rule 3745-21-07, the requirement to comply with the previous 21-07(G)(2) rule provisions still exists as part of the federally-approved SIP for Ohio. The following terms and conditions shall become void after U.S. EPA approves the rule revision: b)(1)d.

c) Operational Restrictions

(1) The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

(2) The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream and downstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees

Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

(2) The permittee shall collect and record the following information each day:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

(3) The permittee shall collect and record the following information each month:

a. The name and identification code of each organic solvent material employed in each batch.

b. The number of gallons of each organic compound solvent material employed in each batch.

c. The density of each organic compound solvent material employed, in pounds per gallon.

d. The pounds of organic compound solvent material employed in each batch, i.e., d)(3)b. X d)(3)c.

e. The monthly before-control OC emission rate for all organic compound solvent materials employed, in pounds per month, i.e., the summation of d)(3)d. for all batches made in P019 during the month.

f. The monthly controlled OC emission rate for all organic compound solvent materials, in pounds per month, i.e., the value in d)(3)e. multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.

g. The rolling 12-month emissions of OC, i.e., the summation of d)(3)f. for the previous 12-month period divided by 2000 lbs/ton.

(4) The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and record equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in f)(2).

(5) Whenever the monitored average temperature of the exhaust gases immediately before the catalyst bed deviates from the range or limit established in accordance with this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. the date and time the deviation began;

b. the magnitude of the deviation at that time;

c. the date the investigation was conducted;

d. the name(s) of the personnel who conducted the investigation; and

e. the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range(s)/limit(s) specified in this permit, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

a. a description of the corrective action;

b. the date corrective action was completed;

c. the date and time the deviation ended;

d. the total period of time (in minutes) during which there was a deviation;

e. the temperature of the exhaust gases immediately before the catalyst bed immediately after the corrective action was implemented; and

f. the name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The temperature ranges are effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA District Office or local air agency. The permittee may request revisions to the permitted temperature range(s) based upon information obtained during future performance tests that demonstrate compliance with the allowable emission rate(s) of the controlled pollutant(s). In addition, approved revisions to the temperature range(s) will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

(6) The permittee shall calculate and maintain monthly records of the OC emissions and the rolling 12-month emissions of OC.

(7) The permit to install for this emissions unit (P019) was evaluated based on the actual materials (typically coatings and cleanup 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 for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

Pollutant: Cyclohexane

TLV (mg/m3): 344

Maximum Hourly Emission Rate (lbs/hr): 0.42

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 19.64

MAGLC (ug/m3): 3,442

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 still 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 (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

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.).

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(VV)(1)(a)(ii), and a modification of the existing permit to install will not

be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

(8) 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 its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy".

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.

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation (excursion) reports that identify:

a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:

i. all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance;

ii. all exceedances of the rolling, 12-month emission limitation for OC;

iii. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer.

b. the probable cause of each deviation (excursion);

c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and

d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.

The quarterly reports shall be submitted, electronically through Ohio EPA Air Services, each year by January 31 (covering October to December), April 30 (covering January to

March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate District Office or local air agency).

(2) The permittee shall identify in the annual permit evaluation report the following information concerning the operations of the catalytic oxidizer during the 12-month reporting period for this/these emissions unit(s):

a. each period of time (start time and date, and end time and date) when the average temperature of the exhaust gases immediately before the catalyst bed was outside of the acceptable ranges;

b. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer;

c. each incident of deviation described in e)(2)a. or e)(2)b. where a prompt investigation was not conducted;

d. each incident of deviation described in e)(2)a. or e)(2)b. where prompt corrective action, that would bring the emissions unit(s) into compliance and/or the temperature of the exhaust gases immediately before the catalyst bed into compliance with the acceptable range(s), was determined to be necessary and was not taken;

e. each incident of deviation described in e)(2)a. or e)(2)b. where proper records were not maintained for the investigation and/or the corrective action(s), as identified in the monitoring and record keeping requirements of this permit; and

(3) Annual Permit Evaluation Report (PER) forms will be mailed to the permittee at the end of the reporting period specified in the Authorization section of this permit. The permittee shall submit the PER in the form and manner provided by the director by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

(4) The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the Megtec catalytic oxidizer system required in f)(2) of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

f) Testing Requirements

(1) Compliance with the emission limitation(s) in b)(1) of these terms and conditions shall be determined in accordance with the following methods:

a. Emission Limitation

OC emissions from this emissions unit shall not exceed 0.41 lbs/hr.

Applicable Compliance Method

Compliance shall be determined by performance testing as specified in f)(3).

b. Emission Limitation

Organic compound (OC) emissions from this emissions unit shall not exceed 1.34 TPY OC, based on a rolling, 12-month summation.

Applicable Compliance Method

Compliance shall be determined by the recordkeeping as specified in d)(3).

(2) The permittee shall conduct, or have conducted, on an annual basis (every 10 to 18 months), either catalyst activity test, emissions testing, or catalyst replacement on the (Megtec/CSM) catalytic oxidizer system in accordance with the (Megtec/CSM) "Catalyst Sampling and Catalyst Testing" protocol. An Intent to Test notification shall not be required for testing of catalyst activity and catalyst replacement.

(3) The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

a. The emission testing shall be conducted 6 months prior to permit renewal.

b. The emission testing shall be conducted to demonstrate compliance with the demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for OC.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):

Method 18 of 40 CFR Part 60, Appendix A, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds.

Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 of the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95")

d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

e. Not later than 60 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the appropriate Ohio EPA District Office or local air agency. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval prior to the test(s) may result in the Ohio EPA District Office's or local air agency's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA District Office or local air agency shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

g) Miscellaneous Requirements

(1) The terms and conditions of this permit to install and operate shall supersede all terms and conditions for emissions unit P019 in PTI 08-04572 issued august 12, 2004 and represent no change in emissions.

4. Emissions Unit Group - Pharmaceutical Fluid Bed Coaters: P008, P014, P015, P020

EU ID	Operations, Property and/or Equipment Description
P008	Glatt Fluid Bed Coater GPCG-5- for pharmaceuticals, controlled by catalytic oxidizer
P014	Pharmaceutical pan coater controlled by a catalytic oxidizer
P015	Glatt Pharmaceutical fluid bed coater contolled by a catalytic oxidizer
P020	Glatt Fluid Bed Coater GPCG-3 for pharmaceuticals, controlled by catalytic oxidizer.

a) This permit document constitutes a permit-to-install issued in accordance with ORC 3704.03(F) and a permit-to-operate issued in accordance with ORC 3704.03(G).

(1) For the purpose of a permit-to-install document, the emissions unit terms and conditions identified below are federally enforceable with the exception of those listed below which are enforceable under state law only.

a. d)(7) and d)(8).

(2) For the purpose of a permit-to-operate document, the emissions unit terms and conditions identified below are enforceable under state law only with the exception of those listed below which are federally enforceable.

a. None.

b) Applicable Emissions Limitations and/or Control Requirements

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

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
a.	OAC rule 3745-31-05(A)(3)	Organic compound (OC) emissions from this emissions unit shall not exceed 0.68 lbs/hr. See b)(2)d. for emission control measures.
b.	OAC rule 3754-31-05(D) (Synthetic Minor to avoid Title V)	OC emissions from emissions unit shall not exceed 2.23 TPY as a rolling 12-month summation See b)(2)d. for emission control measures.
c.	OAC rule 3745-21-07(M)(1) and (M)(2).	The control requirement specified by this rule is less stringent than the control requirement established pursuant to OAC rule 3745-31-05(A)(3).

	Applicable Rules/Requirements	Applicable Emissions Limitations/Control Measures
d.	OAC rule 3745-21-07(G)(2) effective 6/15/1999	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3). See b)(2)(e).

(2) Additional Terms and Conditions

a. The hourly OC emissions limit was established to reflect the controlled potential to emit for this emissions unit. Therefore, it is not necessary to develop record keeping and/or reporting requirements to ensure compliance with this short term emissions limitation.

b. The emissions of OC from this emissions unit shall not exceed 2.23 tons per year, based upon a rolling, 12-month summation of the monthly emissions.

c. All of the OC emissions from this emissions unit shall be vented to the/a catalytic oxidizer that shall meet the operational, monitoring, and record keeping requirements of this permit, when the emissions unit is in operation.

d. The OC emissions from this emissions unit shall be controlled through the application of a catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [The Megtec catalytic oxidizer system is a common OC control device for emissions units P001, P008, P014, P015, P017, P019, and P020.].

e. On February 18, 2008, OAC rule 3745-21-07 was partially revised; therefore, the 21-07(G)(2) rule that was in effect prior to this date is no longer part of the State regulations. On April 4, 2008, the rule revision was submitted to the U.S. EPA as a revision to Ohio's State Implementation Plan (SIP); however, until the U.S. EPA approves the revision to OAC rule 3745-21-07, the requirement to comply with the previous 21-07(G)(2) rule provisions still exists as part of the federally-approved SIP for Ohio. The following terms and conditions shall become void after U.S. EPA approves the rule revision: b)(1)d.

c) Operational Restrictions

(1) The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

(2) The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.

d) Monitoring and/or Recordkeeping Requirements

(1) The permittee shall operate and maintain temperature monitors and recorders which measure and record the temperature immediately upstream and downstream of the oxidizer's catalyst bed at least every 15 minutes during the period in which the catalytic oxidizer is functioning in achieving the required OC removal. Units shall be in degrees Fahrenheit. The monitoring and recording devices shall be capable of accurately measuring the desired parameter. The temperature monitors and recorders shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

(2) The permittee shall collect and record the following information each day:

a. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

b. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.

(3) The permittee shall collect and record the following information each month:

a. The name and identification code of each organic solvent material employed in each batch.

b. The number of gallons of each organic compound solvent material employed in each batch.

c. The density of each organic compound solvent material employed, in pounds per gallon.

d. The pounds of organic compound solvent material employed in each batch, i.e., d)(3)b. X d)(3)c.

e. The monthly before-control OC emission rate for all organic compound solvent materials employed, in pounds per month, i.e., the summation of d)(3)d. for all batches made during the month.

f. The monthly controlled OC emission rate for all organic compound solvent materials, in pounds per month, i.e., the value in d)(3)e. multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.

g. The rolling 12-month emissions of OC, i.e., the summation of d)(3)f. for the previous 12-month period divided by 2000 lbs/ton.

(4) The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and

checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and record equipment. The checks of associated equipment shall be performed in accordance with the manufacturer's recommendations. Repair and replacement of equipment shall be performed as necessitated by the inspection.

The permittee shall maintain a record of the results of each annual inspection, as well as the results of each catalyst activity test required in f)(2).

(5) Whenever the monitored average temperature of the exhaust gases immediately before the catalyst bed deviates from the range or limit established in accordance with this permit, the permittee shall promptly investigate the cause of the deviation. The permittee shall maintain records of the following information for each investigation:

a. the date and time the deviation began;

b. the magnitude of the deviation at that time;

c. the date the investigation was conducted;

d. the name(s) of the personnel who conducted the investigation; and

e. the findings and recommendations.

In response to each required investigation to determine the cause of a deviation, the permittee shall take prompt corrective action to bring the operation of the control equipment within the acceptable range(s)/limit(s) specified in this permit, unless the permittee determines that corrective action is not necessary and documents the reasons for that determination and the date and time the deviation ended. The permittee shall maintain records of the following information for each corrective action taken:

a. a description of the corrective action;

b. the date corrective action was completed;

c. the date and time the deviation ended;

d. the total period of time (in minutes) during which there was a deviation;

e. the temperature of the exhaust gases immediately before the catalyst bed immediately after the corrective action was implemented; and

f. the name(s) of the personnel who performed the work.

Investigation and records required by this paragraph do not eliminate the need to comply with the requirements of OAC rule 3745-15-06 if it is determined that a malfunction has occurred.

The temperature ranges are effective for the duration of this permit, unless revisions are requested by the permittee and approved in writing by the appropriate Ohio EPA District Office or local air agency. The permittee may request revisions to the permitted temperature range(s) based upon information obtained during future performance tests

that demonstrate compliance with the allowable emission rate(s) of the controlled pollutant(s). In addition, approved revisions to the temperature range(s) will not constitute a relaxation of the monitoring requirements of this permit and may be incorporated into this permit by means of an administrative modification.

(6) The permittee shall calculate and maintain monthly records of the OC emissions and the rolling 12-month emissions of OC.

(7) The permit to install for this emissions unit (P008, P014, P015 and P020) was evaluated based on the actual materials (typically coatings and cleanup 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 for each pollutant emitted by this emissions unit using data from the permit to install application and the SCREEN 3.0 model (or other Ohio EPA approved model). The predicted 1-hour maximum ground-level concentration from the use of the SCREEN 3.0 model was compared to the Maximum Acceptable Ground-Level Concentration (MAGLC). The following summarizes the results of the modeling for the "worst case" pollutant(s):

<u>P008</u>

Pollutant: Isopropyl Alcohol

TLV (ug/m3): 819,468

Maximum Hourly Emission Rate (lbs/hr): 0.68

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 32.58

MAGLC (ug/m3): 8,195

<u>P014</u>

Pollutant: Methanol

TLV (ug/m3): 261,758

Maximum Hourly Emission Rate (lbs/hr): 0.66

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 187.5

MAGLC (ug/m3): 6232.33

<u>P015</u>

Pollutant: IPA

TLV (ug/m3): 981,590

Maximum Hourly Emission Rate (lbs/hr): 0.68

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 797.0

MAGLC (ug/m3): 23,371

<u>P020</u>

Pollutant: Isopropyl Alcohol

TLV (ug/m3): 983,070

Maximum Hourly Emission Rate (lbs/hr): 0.68

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m3): 172.8

MAGLC (ug/m3): 23,410

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 still 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 (typically for coatings or cleanup materials), or the use of new materials, that would result in the emission of a compound with a lower Threshold Limit Value (TLV), as indicated in the most recent version of the handbook entitled "American Conference of Governmental Industrial Hygienists (ACGIH)," than the lowest TLV value previously modeled;

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.).

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(VV)(1)(a)(ii), and a modification of the existing permit to install will not be required. If the change(s) is (are) defined as a modification under other provisions of the modification definition (other than (VV)(1)(a)(ii)), then the permittee shall obtain a final permit to install prior to the change.

(8) 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 its evaluation and determination that the changed emissions unit still satisfies the "Air Toxic Policy".

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.

e) Reporting Requirements

(1) The permittee shall submit quarterly deviation (excursion) reports that identify:

a. all deviations (excursions) of the following emission limitations, operational restrictions and/or control device operating parameter limitations that restrict the potential to emit (PTE) of any regulated air pollutant and have been detected by the monitoring, record keeping and/or testing requirements in this permit:

i. all 24-hour averaging periods when the emissions unit was in operation during which the average temperature of the exhaust gases immediately before the catalyst bed was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance;

ii. all exceedances of the rolling, 12-month emission limitation for OC;

iii. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer.

b. the probable cause of each deviation (excursion);

c. any corrective actions that were taken to remedy the deviations (excursions) or prevent future deviations (excursions); and

d. the magnitude and duration of each deviation (excursion).

If no deviations (excursions) occurred during a calendar quarter, the permittee shall submit a report that states that no deviations (excursions) occurred during the quarter.

The quarterly reports shall be submitted, electronically through Ohio EPA Air Services, each year by January 31 (covering October to December), April 30 (covering January to March), July 31 (covering April to June), and October 31 (covering July to September), unless an alternative schedule has been established and approved by the Director (the appropriate District Office or local air agency).

(2) The permittee shall identify in the annual permit evaluation report the following information concerning the operations of the catalytic oxidizer during the 12-month reporting period for this/these emissions unit(s):

a. each period of time (start time and date, and end time and date) when the average temperature of the exhaust gases immediately before the catalyst bed was outside of the acceptable ranges;

b. any period of time (start time and date, and end time and date) when the emissions unit(s) was/were in operation and the process emissions were not vented to the catalytic oxidizer;

c. each incident of deviation described in e)(2)a. or e)(2)b. where a prompt investigation was not conducted;

d. each incident of deviation described in e)(2)a. or e)(2)b. where prompt corrective action, that would bring the emissions unit(s) into compliance and/or the temperature of the exhaust gases immediately before the catalyst bed into compliance with the acceptable range(s), was determined to be necessary and was not taken;

e. each incident of deviation described in e)(2)a. or e)(2)b. where proper records were not maintained for the investigation and/or the corrective action(s), as identified in the monitoring and record keeping requirements of this permit; and

(3) Annual Permit Evaluation Report (PER) forms will be mailed to the permittee at the end of the reporting period specified in the Authorization section of this permit. The permittee shall submit the PER in the form and manner provided by the director by the due date identified in the Authorization section of this permit. The permit evaluation report shall cover a reporting period of no more than twelve-months for each air contaminant source identified in this permit.

(4) The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the Megtec catalytic oxidizer system required in f)(2) of this permit. The report shall also include a proposed course of action for the catalyst. Proposed actions may include no action, catalyst re-testing, or catalyst replacement, and shall be based on the catalyst activity test(s), manufacturer's recommendations, and engineering assessments. This annual report shall be submitted within 45 days after each catalyst activity test is performed.

f) Testing Requirements

(1) Compliance with the emission limitation(s) in b)(1) of these terms and conditions shall be determined in accordance with the following methods:

a. <u>Emission Limitation</u>

OC emissions from this emissions unit shall not exceed 0.68 lbs/hr.

<u>Applicable Compliance Method</u>

Compliance shall be determined by performance testing as specified in f)(3).

b. Emission Limitation

OC emissions from this emissions unit shall not exceed 2.23 TPY OC, based on a rolling, 12-month summation.

Applicable Compliance Method

Compliance shall be determined by the recordkeeping as specified in d)(3).

(2) The permittee shall conduct, or have conducted, on an annual basis (every 10 to 18 months), either catalyst activity test, emissions testing, or catalyst replacement on the (Megtec/CSM) catalytic oxidizer system in accordance with the (Megtec/CSM) "Catalyst Sampling and Catalyst Testing" protocol. An Intent to Test notification shall not be required for testing of catalyst activity and catalyst replacement.

(3) The permittee shall conduct, or have conducted, emission testing for this emissions unit in accordance with the following requirements:

a. The emission testing shall be conducted 6 months prior to permit renewal.

b. The emission testing shall be conducted to demonstrate compliance with the demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for OC.

c. The following test method(s) shall be employed to demonstrate compliance with the allowable mass emission rate(s):

Method 18 of 40 CFR Part 60, Appendix A, as well as Method 25 or 25 A of 40 CFR Part 60, Appendix A, as appropriate, and the test method(s) which must be employed to demonstrate compliance with the overall control efficiency limitation for organic compounds.

Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

The control efficiency (i.e., the percent reduction in mass emissions between the inlet and outlet of the control system) shall be determined in accordance with the test methods and procedures specified in OAC rule 3745-21-10 of the approved alternative test protocol (e.g., "the mass balance protocol approved on 10/25/95")

d. The test(s) shall be conducted while the emissions unit is operating at or near its maximum capacity, unless otherwise specified or approved by the appropriate Ohio EPA District Office or local air agency.

e. Not later than 60 days prior to the proposed test date(s), the permittee shall submit an "Intent to Test" notification to the appropriate Ohio EPA District Office or local air agency. The "Intent to Test" notification shall describe in detail the proposed test methods and procedures, the emissions unit operating parameters, the time(s) and date(s) of the test(s), and the person(s) who will be conducting the test(s). Failure to submit such notification for review and approval

prior to the test(s) may result in the Ohio EPA District Office's or local air agency's refusal to accept the results of the emission test(s).

f. Personnel from the appropriate Ohio EPA District Office or local air agency shall be permitted to witness the test(s), examine the testing equipment, and acquire data and information necessary to ensure that the operation of the emissions unit and the testing procedures provide a valid characterization of the emissions from the emissions unit and/or the performance of the control equipment.

g. A comprehensive written report on the results of the emissions test(s) shall be signed by the person or persons responsible for the tests and submitted to the appropriate Ohio EPA District Office or local air agency within 30 days following completion of the test(s). The permittee may request additional time for the submittal of the written report, where warranted, with prior approval from the appropriate Ohio EPA District Office or local air agency.

g) Miscellaneous Requirements

(1) The terms and conditions of this permit to install and operate shall supersede all terms and conditions for emissions units P008 in PTI 08-04603 issued August 12, 2004 and P020 in PTI 08-04680 issued June 16, 2005 and represents no change in emissions. The terms and conditions of this permit to install and operate shall supersede all terms and conditions for emissions units P014 and P015 in PTI 08-04386 issued December 29, 2006 and represents a 0.66 TPY decrease in OC emissions for P014 and a 0.76 TPY decrease in OC emissions for P015. This permit is also being modified to change recordkeeping requirements for emissions unit P014 and P015 from 365-day rolling OC records to 12-month rolling OC records.