



State of Ohio Environmental Protection Agency

**RE: FINAL PERMIT TO INSTALL
MONTGOMERY COUNTY**

CERTIFIED MAIL

Street Address:

122 S. Front Street

Lazarus Gov. Center TELE: (614) 644-3020 FAX: (614) 644-2329

Mailing Address:

Lazarus Gov. Center
P.O. Box 1049

Application No: 08-04386

DATE: 8/27/2002

Eurand America Inc
Dane Marsee
845 Center Dr
Vandalia, OH 45377-3129

Enclosed please find an Ohio EPA Permit to Install which will allow you to install the described source(s) in a manner indicated in the permit. Because this permit contains several conditions and restrictions, I urge you to read it carefully.

The Ohio EPA is urging companies to investigate pollution prevention and energy conservation. Not only will this reduce pollution and energy consumption, but it can also save you money. If you would like to learn ways you can save money while protecting the environment, please contact our Office of Pollution Prevention at (614) 644-3469.

You are hereby notified that this action by the Director is final and may be appealed to the Ohio Environmental Review Appeals Commission pursuant to Chapter 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. It must be filed within thirty (30) days after the notice of the Directors action. A copy of the appeal must be served on the Director of the Ohio Environmental Protection Agency within three (3) days of filing with the Commission. An appeal may be filed with the Environmental Review Appeals Commission at the following address:

Environmental Review Appeals Commission
236 East Town Street, Room 300
Columbus, Ohio 43215

Very truly yours,

Michael W. Ahern, Supervisor
Field Operations and Permit Section
Division of Air Pollution Control

cc: USEPA

RAPCA



**Permit To Install
Terms and Conditions**

**Issue Date: 8/27/2002
Effective Date: 8/27/2002**

FINAL PERMIT TO INSTALL 08-04386

Application Number: 08-04386
APS Premise Number: 0857171794
Permit Fee: **\$1700**
Name of Facility: Eurand America Inc
Person to Contact: Dane Marsee
Address: 845 Center Dr
Vandalia, OH 45377-3129

Location of proposed air contaminant source(s) [emissions unit(s)]:
**845 Center Dr
Vandalia, Ohio**

Description of proposed emissions unit(s):
**coated pharmaceuticals P013, chapter 31 replacing 08-04112 issued 12-22-99; fluid bed mod. P017
requesting increase in solvent spray rate, chapter 31 replacing 08-04305 issued 11-6-01.**

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

This permit is granted subject to the conditions attached hereto.

Ohio Environmental Protection Agency

Director

Part I - GENERAL TERMS AND CONDITIONS

A. Permit to Install General Terms and Conditions

1. Compliance Requirements

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

2. Reporting Requirements Related to Monitoring and Recordkeeping Requirements

The permittee shall submit required reports in the following manner:

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

3. Records Retention Requirements

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

4. Inspections and Information Requests

The Director of the Ohio EPA, or an authorized representative of the Director, may, subject to the safety requirements of the permittee and without undue delay, enter upon the premises of this source at any reasonable time for purposes of making inspections, conducting tests, examining records or reports pertaining to any emission of air contaminants, and determining compliance with any applicable State air pollution laws and regulations and the terms and conditions of this permit. The permittee shall furnish to the Director of the Ohio EPA, or an authorized

representative of the Director, upon receipt of a written request and within a reasonable time, any information that may be requested to determine whether cause exists for modifying, reopening or revoking this permit or to determine compliance with this permit. Upon verbal or written request, the permittee shall also furnish to the Director of the Ohio EPA, or an authorized representative of the Director, copies of records required to be kept by this permit.

5. Scheduled Maintenance/Malfunction Reporting

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

6. Permit Transfers

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

7. Air Pollution Nuisance

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

8. Termination of Permit to Install

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

9. Construction of New Sources(s)

The proposed emissions unit(s) shall be constructed in strict accordance with the plans and application submitted for this permit to the Director of the Ohio Environmental Protection Agency. There may be no deviation from the approved plans without the express, written approval of the Agency. Any deviations from the approved plans or the above conditions may lead to such sanctions

and penalties as provided under Ohio law. Approval of these plans does not constitute an assurance that the proposed facilities will operate in compliance with all Ohio laws and regulations. Additional facilities shall be installed upon orders of the Ohio Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

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

10. Public Disclosure

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

11. Applicability

This Permit to Install is applicable only to the emissions unit(s) identified in the Permit to Install. Separate application must be made to the Director for the installation or modification of any other emissions unit(s).

12. Best Available Technology

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

13. Source Operation and Operating Permit Requirements After Completion of Construction

This facility is permitted to operate each source described by this Permit to Install for a period of up to one year from the date the source commenced operation. This permission to operate is granted only if the facility complies with all requirements contained in this permit and all applicable air pollution laws, regulations, and policies. Pursuant to OAC Chapter 3745-35, the permittee shall submit a complete operating permit application within thirty (30) days after commencing operation of the emissions unit(s) covered by this permit.

Eurand America Inc
PTI Application: 08-04386
Issued: 8/27/2002

Facility ID: 0857171794

14. Construction Compliance Certification

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

15. Fees

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

B. Permit to Install Summary of Allowable Emissions

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

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

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	56.53

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P001 - 200, 500, and 1000 gallon pharmaceutical microencapsulation systems and dryers, controlled by a catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	3.20 lbs/hr organic compounds (OC) and 76.7 lbs OC/day See Section A.2.a below for emission control measures
	OAC rule 3745-35-07(B)	14 TPY OC, as a rolling, 365-day summation See Section A.2.a below for emission control measures
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A).

2. Additional Terms and Conditions

- 2.a 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. [This catalytic oxidizer system is a common OC control device for emissions units P001, P014, P015, and P017].

B. 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. The average temperature difference across the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

2. The average temperature of the chilled water supply shall not exceed 46 degrees F.

C. 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.

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. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.
 - c. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall operate and maintain a temperature monitor and recorder which measures and records the temperature of the chilled water supply at least every 15 minutes during the period when the emissions unit is in operation. The temperature monitor shall be connected to an alarm system that will sound and be relayed and notify the control room personnel if the temperature of the condensate water exceeds 46 degrees F. The temperature monitor and alarm system shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, instructions and operating manuals.

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

- a. The permittee shall record all instances when the operator is notified by the alarm system of a temperature deviation as identified in this permit.
 - b. The permittee shall maintain a log of condensate temperatures which are observed and recorded each 8 hour shift.
3. The permittee shall collect and record the following information each day:
- 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., (b) X (c).
 - e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined multiplied by a solvent recovery factor of (1-0.95)*.
- *In-process solvent recovery from solvent filtration and condensation is assumed to be 95%. The permittee shall maintain an annual solvent inventory that calculates actual solvent recovery efficiency.
- f. The daily controlled OC emission rate for all organic compound solvent materials, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled organic compound emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 3.20 lbs/hr, and the actual average hourly controlled

organic compound emissions for each such day.

- b. An identification of each day during which the controlled organic compound emissions rate exceeded 76.7 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of 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.
 - d. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.
 - e. An identification of all instances when the operator is notified by the alarm system of a temperature deviation as identified in Section C.2. of this permit.
 - f. An identification of each day during which the rolling, 365-day OC emission rate exceeded 14 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include 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 submit annual reports which specify the solvent recovery efficiency and the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emission Limitation-
3.20 lbs/hr OC

Applicable Compliance Method-

Eurand America Inc
PTI Application: 08 04286
Issued

Facility ID: 0857171794

Emissions Unit ID: **P001**

Compliance shall be determined by performance testing as specified in Section E.2. of this permit and recordkeeping as specified in Section C.3. of this permit.

- b. Emission Limitation-
76.7 lbs/day OC

Applicable Compliance Method-
Compliance shall be determined by performance testing as specified in Section E.2. of this permit and recordkeeping as specified in Section C.3. of this permit.

- c. Emission Limitation-
14 TPY OC, based on a rolling, 365-day summation

Applicable Compliance Method-
Compliance shall be determined by the recordkeeping as specified in Section C.3. of this permit.
2. The permittee shall conduct, or have conducted, emissions testing on this emissions unit in accordance with the following requirements:
 - a. The emissions testing shall be conducted within ninety days after permit issuance.
 - b. The emissions testing shall be conducted to demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for organic compounds.
 - 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.

Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. 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 tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be

permitted to witness the tests, 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.

A comprehensive written report on the results of the emissions tests 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.

F. Miscellaneous Requirements

1. The requirements of this permit supercede the requirements of PTI 08-04187, issued September 12, 2000. This permit is being modified to separate multiple emissions sources previously combined under emissions unit P001 and also to alter monitoring and recordkeeping requirements. Allowable OC emissions from P001 are being decreased by 13.37 TPY as a result of this modification.
2. The following terms and conditions are federally enforceable: Sections A.2.a, B.1., C.1., C.3., D.1.c-d, D.1.f., D.2., D.3., E.1.c., and E.2.
3. Modeling to demonstrate compliance with the Ohio EPA's "Air Toxic Policy" was not necessary because the emissions unit's net increase in annual emissions from this permit modification for each toxic compound will be less than 1.0 ton. OAC Chapter 3745-31 requires permittees to apply for and obtain a new or modified permit to install prior to making a "modification" as defined by OAC rule 3745-31-01. The permittee is hereby advised that changes in the composition of the materials, or use of new materials, that would cause the emissions of any pollutant that has a listed TLV to increase to above 1.0 ton per year may require the permittee to apply for and obtain a new permit to install.

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P012 - Pharmaceuticals processing system, controlled by a HEPA filter and catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	5.0 lbs/hour organic compounds (OC) and 92 lbs OC/day See Section A.2.a below for emission control measures
	OAC rule 3745-35-07(B)	16.8 TPY OC, as a rolling, 365-day summation See Section A.2.a below for emission control measures
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- 2.a The organic compound emissions from emissions unit P012 shall be controlled through the application of a HEPA filter for particulate removal and a catalytic oxidizer. The catalytic oxidizer shall operate at a destruction efficiency of at least 98 percent [This catalytic oxidizer system is a common OC control device for emissions units P012 and P013].

B. 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.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain a temperature monitor and recorder which measures and records the temperature immediately upstream 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 monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

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.
2. The permittee shall collect and record the following information each day when the emissions unit is in operation:
 - 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., (b) X (c).
 - e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
3. The permittee shall perform a preventive maintenance inspection of the catalytic oxidizer on an annual basis to evaluate the performance of each catalyst bed. The inspection shall consist of internal and visual inspections as detailed in the preventive maintenance checklist submitted to the Regional Air Pollution Control Agency on April 12, 2002, and shall include a physical inspection of each unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording 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. Samples of catalyst material shall be collected from the catalyst bed to perform the catalyst activity test described in Section E.2. of this permit.
- 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 Section E.2. of this permit.
4. 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.

5. 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.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that shall include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 5.0 lbs/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emissions rate exceeded 92 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average combustion temperature within the catalytic oxidizer was more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.
 - d. An identification of each day during which the rolling, 365-day OC emission rate exceeded 16.8 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include 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 submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.
4. The permittee shall submit an annual report that includes the results of the annual catalyst activity test required in Section E.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, catalyst cleaning, 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.

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be

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Euran

PTI A

Issued: 8/27/2002

Emissions Unit ID: **P012**

determined in accordance with the following methods:

- a. Emission Limitation -
5.0 lbs/hr OC

Applicable Compliance Method -
 Compliance shall be determined by recordkeeping as specified in Section C.2. of this permit.

- b. Emission Limitation -
 92 lbs/day OC

Applicable Compliance Method -
 Compliance shall be determined by recordkeeping as specified in Section C.2. of this permit.

- c. Emission Limitation -
 16.8 TPY OC

Applicable Compliance Method -
 Compliance shall be determined by recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.

2. The permittee shall conduct, or have conducted, an annual catalyst activity test using the catalyst sample(s) collected during the annual preventive maintenance inspection described in section C.3. An intent to test notification shall not be required for the testing noted in this section. The procedure for the catalyst activity test shall be in accordance with the "CSM Catalyst Sampling and Catalyst Testing" protocol as submitted to the Regional Air Pollution Control Agency on April 12, 2002.
3. Emissions testing of P012, completed on June 11, 2001, demonstrated compliance with the mass allowable emission rates specified in Section A.1. and the catalytic oxidizer destruction efficiency of at least 98 percent as specified in Section A.2.a. of this permit. No further emissions testing is required by this PTI.

F. Miscellaneous Requirements

1. This permit to install is a Chapter 31 modification of PTI 08-03735, issued January 21, 1998, and represents an increase in the annual allowable emissions of 4.8 TPY OC.
2. The following terms and conditions are federally enforceable: Sections A.2.a, B.1-2., C.1-3., D.1.c-d., D.2-4., E.1.c., and E.2.

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P013 - Pharmaceutical bead preparation room with enclosed granulator, two extruders, two spheronizers, and four drying ovens, with catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	0.08 lb/hr organic compounds (OC), 1.92 lbs/day OC, and 0.35 TPY OC
		See Section A.2.a. below for emission control measures
		The requirements of this rule also include compliance with the requirements of OAC rules 3745-21-07(G)(2).
	OAC rule 3745-21-07(G)(2)	See Section A.2.b. below

2. Additional Terms and Conditions

- 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. [This catalytic oxidizer system is a common OC control device for emissions units P012 and P013].

B. Operational Restrictions

- 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.

3. Emissions unit P013 shall be equipped with a permanent total enclosure (PTE)* that shall be installed and operated in accordance with 40 CFR, Part 51, Appendix M, Method 204. The PTE shall meet the following criteria:
 - a. Any "Natural Draft Opening" (NDO)* shall be at least 4 equivalent diameters from each VOC emission point.
 - b. The total area of all NDOs shall not exceed 5 percent of the surface area of the enclosure's four walls, floor and ceiling.
 - c. The average facial velocity (FV) of air through all NDOs shall be at least 3,600 m/hr (200 fpm) which corresponds to a pressure differential of 0.007 inch of water (the direction of air through all NDOs shall be into the enclosure).
 - d. All access doors and windows whose areas are not included in paragraph (b) and are not included in the calculation in paragraph (c) shall be closed during routine operation.
 - e. All VOC emissions must be captured and contained for discharge through the VOC control device.

By satisfying the criteria above for establishing a permanent total enclosure, the total VOC capture efficiency shall be assumed to be 100%.

* Definitions for PTE and NDO:

Permanent Total Enclosure (PTE) - a permanently installed enclosure that completely surrounds a source of emissions such that all VOC emissions are captured and contained for discharge through a control device.

Natural Draft Opening (NDO) - any permanent opening in the enclosure that remains open during operation of the facility and is not connected to a duct to which a fan is installed.

4. Emissions unit P013 has demonstrated that it meets the criteria established for a PTE in Method 204. The permittee performed a demonstration on June 11, 2001 to show that the PTE could not be compromised, under normal plant conditions, when the emissions unit was in operation (i.e., the air flow through the PTE to the control device was always maintained under negative pressure even when all additional egress points (non-natural draft opening) which could affect the PTE were opened). Therefore, the permittee will not be required to perform additional monitoring, record keeping and reporting requirements to ensure the ongoing integrity of the PTE for this emissions unit.

C. Monitoring and/or Recordkeeping Requirements

1. The permittee shall operate and maintain a temperature monitor and recorder which measures and records the temperature immediately upstream 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 monitor and recorder shall be installed, calibrated, operated and maintained in accordance with the manufacturer's recommendations, with any modifications deemed necessary by the permittee.

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.
2. The permittee shall collect and record the following information each day:
 - a. The number of sub-batches*.
 - b. The number of gallons of each organic compound solvent material employed in each sub-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 sub-batch, i.e., (b) X (c).
 - e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.

- g. The total number of hours the unit was in operation.
- h. The average hourly controlled organic compound emission rate, in pounds per hour (average), i.e., (f)/(g).

* For emissions units P013, product is measured in sub-batches. 114 sub-batches comprise a batch. Individual sub-batches are mixed, extruded, and spheronized before being placed into one of four drying ovens. The drying cycle for an oven does not begin until 38 sub-batches have filled that oven to capacity. The drying cycle for the ovens is staggered depending on when each oven is filled.

- 3. The permittee shall perform a preventive maintenance inspection of the catalytic oxidizer on an annual basis to evaluate the performance of each catalyst bed. The inspection shall consist of internal and visual inspections as detailed in the preventive maintenance checklist submitted to the Regional Air Pollution Control Agency on April 12, 2002, and shall include a physical inspection of each unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and recording 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. Samples of catalyst material shall be collected from the catalyst bed to perform the catalyst activity test described in Section E.2. of this permit.

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 Section E.2. of this permit.

D. Reporting Requirements

- 1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that shall include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.08 lb/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emissions rate exceeded 1.92 lbs/day, and the actual controlled organic compound emissions rate for each such day.

Emissions Unit ID: P013

- c. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average combustion temperature within the catalytic oxidizer was 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 permittee shall submit quarterly summaries which include 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 submit an annual report that includes the results of the annual catalyst activity test required in Section E.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, catalyst cleaning, 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.

E. Testing Requirements

1. Compliance with the emission limitation(s) in section A.1. of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emission Limitation -
0.08 lb/hr OC

Applicable Compliance Method -
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit.
 - b. Emission Limitation -
1.92 lbs/day OC

Applicable Compliance Method -
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit.
 - c. Emission Limitation -
0.35 TPY OC

Applicable Compliance Method -
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.
2. The permittee shall conduct, or have conducted, an annual catalyst activity test using the catalyst sample(s) collected during the annual preventive maintenance inspection described in section C.3. An intent to test notification shall not be required for the testing noted in this section. The procedure for the catalyst activity test shall be in accordance with the "CSM Catalyst Sampling and Catalyst Testing" protocol as submitted to the Regional Air Pollution Control Agency on April 12, 2002.
3. Emissions testing of P013, completed on June 11, 2001, demonstrated compliance with the mass allowable emission rates specified in Section A.1. and the catalytic oxidizer destruction efficiency of at least 98 percent as specified in Section A.2.a. of this permit. No further emissions testing is required by this PTI.

F. Miscellaneous Requirements

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PTI Application: 08 01286
Issued

Facility ID: 0857171794

Emissions Unit ID: **P013**

1. Modeling to demonstrate compliance with the Ohio EPA's "Air Toxic Policy" was not necessary because the emissions unit's maximum annual emissions for each toxic compound will be less than 1.0 ton. OAC Chapter 3745-31 requires permittees to apply for and obtain a new or

modified permit to install prior to making a "modification" as defined by OAC rule 3745-31-01. The permittee is hereby advised that changes in the composition of the materials, or use of new materials, that would cause the emissions of any pollutant that has a listed TLV to increase to above 1.0 ton per year may require the permittee to apply for and obtain a new permit to install.

2. The requirements of this permit supercede the requirements of PTI 08-04112, issued December 22, 1999. This permit is being modified to alter monitoring and recordkeeping requirements. There is no change in allowable emission rates for P013 as a result of this modification.

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P014 - a pan coater for pharmaceuticals, controlled by a catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	0.66 lb/hr organic compounds (OC) and 15.84 lbs/day OC See Section A.2.a. below for emission control measures
	OAC rule 3745-35-07(B)	2.89 TPY OC, as a rolling, 365-day summation See Section A.2.a. below for emission control measures
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- 2.a 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. [This catalytic oxidizer system is a common OC control device for emissions units P001, P014, P015, and P017].

B. 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. The average temperature difference across the catalyst bed, for any 24-hour averaging period, when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

C. 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.

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. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.
 - c. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day:
 - 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., (b) X (c).

- e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
3. The permit to install for this emissions unit (P014) 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: 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

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

Emissions Unit ID: **P014**

- 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.

4. 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.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.66 lb/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emissions rate exceeded 15.84 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of 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.

- d. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

- e. An identification of each day during which the rolling, 365-day OC emission rate exceeded 2.89 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include 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 submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emission Limitation-
0.66 lb/hr OC

Applicable Compliance Method-
Compliance shall be determined by performance testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.
 - b. Emission Limitation-
15.84 lbs/day OC

Applicable Compliance Method-
Compliance shall be determined by performance testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.
 - c. Emission Limitation-
2.89 TPY OC, based on a rolling, 365-day summation

Applicable Compliance Method-
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.
2. The permittee shall conduct, or have conducted, emission testing on this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be conducted within ninety days after permit issuance.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for organic compounds.
- 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.
- 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.

Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. 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 tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be permitted to witness the tests, 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.

A comprehensive written report on the results of the emissions tests 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.

F. Miscellaneous Requirements

1. The requirements of this permit supercede the requirements of PTI 08-04135, issued May 24, 2000. This permit is being modified to alter monitoring and recordkeeping requirements. There

is no change in allowable emission rates for P014 as a result of this modification.

2. The following terms and conditions are federally enforceable: A.2.a., B.1., C.1-2., D.1.c-e., D.2-3., E.1.c., and E.2.

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P015 -Glatt Fluid Bed Coater for pharmaceuticals, controlled by catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	0.68 lb/hr organic compounds (OC) and 16.32 lbs OC/day See Section A.2.a. below for emission control measures
	OAC rule 3745-35-07(B)	2.99 TPY OC, as a rolling, 365-day summation See Section A.2.a. below for emission control measures
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- 2.a 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. [This catalytic oxidizer system is a common OC control device for emissions units P001, P014, P015, and P017].

B. Operational Restrictions

Eurand America Inc
PTI Application: 08 01286
Issued

Facility ID: 0857171794

Emissions Unit ID: **P015**

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. The average temperature difference across the catalyst bed,

for any 24-hour averaging period, when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

C. 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.

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. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.
 - c. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day:
 - 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., (b) X (c).

- e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
3. The permit to install for this emissions unit (P015) 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: 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

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

Emissions Unit ID: P015

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.

4. 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.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with paragraph A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emissions rate exceeded 0.68 lb/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emissions rate exceeded 16.32 lbs/day, and the actual controlled organic compound emissions rate for each such day.
 - c. An identification of 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.

- d. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

- e. An identification of each day during which the rolling, 365-day OC emission rate exceeded 2.99 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include 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 submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.

E. Testing Requirements

1. Compliance with the emission limitation(s) in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emission Limitation-
0.68 lb/hr OC

Applicable Compliance Method-
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.
 - b. Emission Limitation-
16.32 lbs/day OC

Applicable Compliance Method-
Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and the recordkeeping as specified in Section C.2. of this permit.
 - c. Emission Limitation-
2.99 TPY OC, based on a rolling, 365-day summation

Applicable Compliance Method-
Compliance shall be determined by the recordkeeping as specified in Section C.2. of this permit and shall be the summation of the daily controlled organic emissions for the calendar year, divided by 2000 lbs/ton.
2. The permittee shall conduct, or have conducted, emission testing on this emissions unit in accordance with the following requirements:

- a. The emissions testing shall be conducted within ninety days after permit issuance.
- b. The emission testing shall be conducted to demonstrate compliance with the allowable mass emission rates and overall control efficiency of 98% for organic compounds.
- 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.
- 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.

Not later than 30 days prior to the proposed test date(s), this facility shall submit an "Intent to Test" notification. 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 tests, and the person(s) who will be conducting the tests. Failure to submit such notification for review and approval prior to the tests may result in the Ohio EPA District Office's or Local Air Agency's refusal to accept the results of the emission tests.

Personnel from the appropriate Ohio EPA District Office or Local Air Agency shall be permitted to witness the tests, 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.

A comprehensive written report on the results of the emissions tests 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.

F. Miscellaneous Requirements

1. The requirements of this permit supercede the requirements of PTI 08-04135, issued May 24, 2000. This permit is being modified to alter monitoring and recordkeeping requirements. There

is no change in allowable emission rates for P015 as a result of this modification.

2. The following terms and conditions are federally enforceable: A.2.a., B.1., C.1-2., D.1.c-e., D.2-3., E.1.c., and E.2.

PART II - SPECIAL TERMS AND CONDITIONS FOR SPECIFIC EMISSIONS UNIT(S)

A. Applicable Emissions Limitations and/or Control Requirements

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

<u>Operations, Property, and/or Equipment</u>	<u>Applicable Rules/Requirements</u>	<u>Applicable Emissions Limitations/Control Measures</u>
P017 - Glatt 120 pharmaceutical spray coater, with catalytic oxidizer *modification	OAC rule 3745-31-05(A)(3)	5.56 lbs/hr organic compounds (OC) and 106.8 lbs OC/day See Section A.2.a. below for emission control measures
	OAC rule 3745-35-07(B)	19.5 TPY OC, as a rolling, 365-day summation See Section A.2.a. below for emission control measures
	OAC rule 3745-21-07(G)(2)	The emission limitation specified by this rule is less stringent than the emission limitation established pursuant to OAC rule 3745-31-05(A)(3).

2. Additional Terms and Conditions

- 2.a 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. [This catalytic oxidizer system is a common OC control device for emissions units P001, P014, P015, and P017].

B. 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. The average temperature difference across the catalyst bed,

for any 24-hour averaging period, when the emissions unit is in operation, shall not be less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

C. 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.

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. Any 24-hour averaging period (when the emissions unit was in operation) during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.
 - c. A log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
2. The permittee shall collect and record the following information each day:
 - 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., (b) X (c).

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- e. The daily before-control OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the summation of (d) for all batches combined.
 - f. The daily controlled OC emission rate for all organic compound solvent materials employed, in pounds per day, i.e., the value in (e) multiplied by a factor of 1 minus the destruction efficiency from the most recent performance test that demonstrated compliance.
 - g. The total number of hours the unit was in operation.
 - h. The average hourly controlled OC emission rate, in pounds per hour (average), i.e., (f)/(g).
 - i. The rolling, 365-day summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 365-day period divided by 2000 lbs/ton.
3. 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 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.

4. 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.

D. Reporting Requirements

1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with Section A.2. of the General Terms and Conditions of this permit, that include the following information:
 - a. An identification of each day during which the average hourly controlled organic compound emission rate exceeded 5.56 lbs/hr, and the actual average hourly controlled organic compound emissions for each such day.
 - b. An identification of each day during which the controlled organic compound emission rate exceeded 106.8 lbs/day, and the actual controlled organic compound emission rate for each such day.
 - c. An identification of 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.

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- d. An identification of all 24-hour averaging periods when the emissions unit was in operation during which the average temperature difference across the catalyst bed was less than 80 percent of the average temperature difference during the most recent emission test that demonstrated the emissions unit was in compliance.

- e. An identification of each day during which the rolling, 365-day OC emission rate exceeded 19.5 tons, and the actual rolling, 365-day OC emission rate for each such day.
2. The permittee shall submit quarterly summaries which include 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 submit annual reports which specify the total organic compound emissions from this emissions unit for the previous calendar year. These reports shall be submitted by January 31 of each year.

E. Testing Requirements

1. Compliance with the emissions limitations in Section A.1. of these terms and conditions shall be determined in accordance with the following methods:
 - a. Emissions Limitation-
5.56 lbs OC/hr OC

Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and by record keeping as specified in Section C. 2. of this permit.
 - b. Emissions Limitation-
106.8 lbs OC/day OC

Compliance shall be determined by emissions testing as specified in Section E.2. of this permit and by record keeping as specified in Section C. 2. of this permit.
 - c. Emissions Limitation-
19.5 TPY OC, based on a rolling 365-day summation

Compliance shall be determined based upon record keeping as specified in Section C.2. of this permit.
2. 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 ninety days after permit issuance.
 - b. The emission testing shall be conducted to demonstrate compliance with the allowable

mass emission rates and overall control efficiency of 98% for organic compounds.

- 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.

- d. 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. The test methods and procedures selected shall be based on a consideration of the diversity of the organic species present and their total concentration, and on a consideration of the potential presence of interfering gases.
- e. 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.

Not later than 30 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).

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.

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.

F. Miscellaneous Requirements

1. This permit to install is a Chapter 31 modification of PTI 08-04305, issued November 6, 2001, and represents an increase in allowable emissions of 1.25 TPY OC.

2. The following terms and conditions are federally enforceable: A.2.a., B.1., C.1-2., D.1.c-e., E.1.c., and E.2.