



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: 08-04578**

**Fac ID: 0857171794**

**DATE: 8/17/2004**

Eurand America Inc  
Dane Marsee  
845 Center Dr  
Vandalia, OH 453770000

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  
309 South Fourth Street, Room 222  
Columbus, Ohio 43215

Sincerely,

Michael W. Ahern, Manager  
Permit Issuance and Data Management Section  
Division of Air Pollution Control

cc: USEPA

RAPCA



**Permit To Install  
Terms and Conditions**

**Issue Date: 8/17/2004  
Effective Date: 8/17/2004**

**FINAL PERMIT TO INSTALL 08-04578**

Application Number: 08-04578  
Facility ID: 0857171794  
Permit Fee: **\$200**  
Name of Facility: Eurand America Inc  
Person to Contact: Dane Marsee  
Address: 845 Center Dr  
Vandalia, OH 453770000

Location of proposed air contaminant source(s) [emissions unit(s)]:

**845 Center Dr  
Vandalia, Ohio**

Description of proposed emissions unit(s):

**modification to increase batch size for the process from a theoretical yield of 456 to 760 kg, chapter 31 replacing 08-04112 issued 12-22-99.**

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

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

**Eurand America Inc**  
**PTI Application: 08-04578**  
**Issued: 8/17/2004**

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Environmental Protection Agency if the proposed sources cannot meet the requirements of this permit or cannot meet applicable standards.

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

**10. Public Disclosure**

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

**11. Applicability**

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

**12. Best Available Technology**

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

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

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

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**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	0.47

## 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 - Bead Preparation and coating of pharmaceuticals (granulator, 2-extruders, 2-spheronizers and 4-drying ovens); with catalytic oxidizer and permanent total enclosure (PTE)	OAC rule 3745-31-05(A)(3)	The organic compound (OC) emissions from this emissions unit shall not exceed 0.15 pound per hour (lb/hr).  The requirements of this rule also include compliance with the requirements of OAC rules 3745-35-07(B).  See Sections A.2.a. through A.2.c below.
<b>* modification</b>	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The organic compound (OC) emissions from this emissions unit shall not exceed 0.47 tons per year (TPY), as a rolling, 12-month summation.  See Section A.2.a below.
	OAC rule 3745-21-07(G)(2) OAC rule 3745-21-07(G)(6)	The limitations and requirements specified by these rules are less stringent than the requirements established pursuant to OAC rule 3745-31-05(A).

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**Euran**

**PTI A**

**Issued: 8/17/2004**

Emissions Unit ID: **P013**

## 2. Additional Terms and Conditions

- 2.a The OC emissions from this emissions unit shall be controlled through the application of either the Megtec catalytic oxidizer system or the CSM catalytic oxidizer system, operating at a minimum of 98% overall OC removal/destruction efficiency. [The Megtec Catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017 and P019. The CSM catalytic oxidizer system is a common OC control device for emissions units P012 and P013.]
- 2.b The PTE serving this emissions unit shall be maintained in such a manner as to meet the criteria established for a PTE in Method 204 (40 CFR Part 51, Appendix M) whenever the emissions unit is in operation.
- 2.c The 0.15 lb/hr of OC emission limitation from the process was established for PTI purposes to reflect the controlled hourly potential to emit for this emissions unit. Therefore, it is not necessary to develop daily record keeping and/or reporting requirements to ensure compliance with the average hourly limit.

## B. Operational Restrictions

- 1. When emissions unit P013 is venting to the CSM catalytic oxidizer the following shall apply:
  - a. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance. [The most recent performance test that demonstrated the emissions unit was in compliance was conducted on May 31, 2001 and June 11, 2001. The test results showed an average inlet temperature of 600 degrees Fahrenheit.]
  - b. The catalytic oxidizer shall be operated and maintained in accordance with the manufacturer's recommendations, instructions, and operating manuals.
- 2. When emissions unit P013 is venting to the Megtec catalytic oxidizer the following shall apply:
  - a. The average temperature of the exhaust gases immediately before the catalyst bed, for any 24-hour averaging period when the emissions unit is in operation, shall not be more than 50 degrees Fahrenheit below the average temperature during the most recent emission test that demonstrated the emissions unit was in compliance.

Emissions Unit ID: **P013**

- b. 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 of the process.
  - e. All VOC emissions must be captured and contained for discharge through a 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. The permittee performed a demonstration of compliance with Method 204 for this emissions unit, P013, on June 11, 2001, to show that the PTE could not be compromised under normal operating conditions. Therefore, unless otherwise determined by the Ohio EPA, it shall be assumed that the PTE for P013 captures 100% of the VOC emissions from the process when the access doors are closed. Except in the case of an emergency, all access doors to the PTE shall remain closed during process operations.

### **C. Monitoring and/or Record keeping Requirements**

1. For each product batch run on this emissions unit, the permittee shall maintain a record of which catalytic oxidizer system the emission unit is vented and the date.
2. When emissions unit P013 is venting to the CSM catalytic oxidizer, 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 which the emissions unit is in operation. 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; and
  - b. a log of the downtime for the capture (collection) system, control device, and monitoring equipment, when the associated emissions unit was in operation.
3. When emissions unit P013 is venting to the Megtec catalytic oxidizer 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 which the emissions unit is in operation. 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; and
- b. a log of the downtime for the capture (collection) system, control device, and monitoring

equipment, when the associated emissions unit was in operation.

4. The permittee shall collect and record the following information each month:
  - a. the total number of batches\*;
  - b. the total number of sub-batches per batch;
  - c. the company name and/or identification for each organic solvent material employed in each batch;
  - d. the number of gallons of each organic solvent material employed in each batch;
  - e. the density of each organic solvent material employed, in pounds per gallon;
  - f. the pounds of organic solvent material employed in each batch, i.e., (d) x (e);
  - g. the monthly before-control OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the summation of (f) for all batches made in P013 during the month;
  - h. the monthly controlled OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the value in (g) multiplied by a factor of 1 minus the control efficiency from the most recent performance test that demonstrated compliance, or 98% until the initial testing is conducted; and
  - i. the rolling, 12-month summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (h) for the previous 12-month period divided by 2000 lbs/ton.

\* For emissions units P013, product is measured in sub-batches. A batch is comprised of up to 190 sub-batches. 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.

5. The permittee shall perform a preventive maintenance inspection of the CSM catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in the preventive maintenance checklist submitted to the Regional Air Pollution Control Agency on April 12, 2002, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and 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.

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.3 of this permit.

6. The permittee shall perform a preventive maintenance inspection of the Megtec catalytic oxidizer on an annual basis to evaluate the performance of the control device. The inspection shall consist of internal and visual inspections as detailed in Megtec's preventive maintenance plan, and shall include a physical inspection of the unit and checks of associated equipment, including but not limited to burners, controls, dampers, valves, and monitoring and 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.

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.3 of this permit.

7. The permittee shall maintain a record of the differential pressure measurements for the permanent total enclosure, as was documented during the demonstration of compliance with Method 204 on June 11, 2001, or any future testing of the permanent total enclosure.

#### **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. For the CSM catalytic oxidizer system:

An identification of all 24-hour averaging period when the emissions unit was in operation and vented to the CSM catalytic oxidizer system 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.

- b. For the Megtec catalytic oxidizer system:

An identification of all 24-hour averaging period when the emissions unit was in operation

Emissions Unit ID: **P013**

and vented to the Megtec catalytic oxidizer system 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.

2. The permittee shall submit quarterly summary reports which include a log of the downtime for the capture (collection) system(s), control device(s), and monitoring equipment(s), when the associated emissions unit was in operation. These summary reports shall be submitted by January 31, April 30, July 31 and October 31 of each year and shall cover the previous calendar quarter.
3. The permittee shall submit an annual report that includes the results of the annual catalyst activity test for the CSM catalytic oxidizer system and the Megtec catalytic oxidizer system required in Section E.3 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 (CSM system only), 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.
4. 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.
5. The permittee shall submit quarterly deviation reports that identify any period of time in which any access door was left opened during process operations; and/or either control device was bypassed.

These summary reports shall be submitted by January 31, April 30, July 31 and October 31 of each year and shall cover the previous calendar quarter.

## **E. Testing Requirements**

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

1. Emission Limitation -  
The organic compound (OC) emissions from this emissions unit shall not exceed 0.15 pound per hour (lb/hr).

Applicable Compliance Method -

Compliance shall be demonstrated by the Engineering Study conducted between October 27, 2003 and January 16, 2004 which established emissions data based on a worst case batch process.

2. Emission Limitation -  
The OC emissions from this emissions unit shall not exceed 0.47 ton per year (TPY).

Applicable Compliance Method -

Compliance shall be determined by the record keeping as specified in Section C.4 of this permit.

3. The permittee shall conduct, or have conducted, an annual catalyst activity test on the CSM catalytic oxidizer system and the Megtec catalytic oxidizer system in accordance with the "CSM Catalyst Sampling and Catalyst Testing" protocol as submitted to the Regional Air Pollution Control Agency on April 12, 2002 and the "Megtec Catalyst Sampling and Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.
4. Emissions testing of the CSM catalytic oxidizer system associated with 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 required in Section A.2.a of this permit. No further emissions testing is required by this PTI..

Emissions unit P013 has demonstrated that it meets the criteria established for a PTE in Method 204. All doors shall remain closed during processing, except for an emergency. If required by the Ohio EPA, Method 204 shall be repeated if the integrity of the permanent total enclosure is in question (i.e.: negative pressure and/or air flow across the natural draft opening(s) into the bead prep room is in question).

5. The permittee shall conduct, or have conducted, emissions testing on the Megtec catalytic oxidizer associated with P013 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 and Method 25 or 25A of 40 CFR Part 60, Appendix A, as appropriate, before and after the catalytic oxidizer, to demonstrate compliance with the destruction efficiency for organic compounds. And if formulation data is not available and/or if required by the regulating agency, Method 24 or 24A of 40 CFR Part 60, Appendix A shall be conducted for the OC content of the solvent materials applied. Alternative U.S. EPA approved test methods may be used with prior approval from the Ohio EPA.

- d. The tests shall be conducted while this 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. 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 08-04386, issued August 27, 2002. This permit is being modified to increase the number of sub-batches per batch; therefore, increasing the allowable emission limitation. This modification represents an increase in emissions of 0.12 TPY OC.

**Eurand America Inc**  
**PTI Application: 08 01570**  
**Issued**

**Facility ID: 0857171794**

Emissions Unit ID: **P013**

3. The following terms and conditions are federally enforceable: Sections A.1 (only the requirements associated with OAC 3745-35-07(B)), A.2.a and c, B.1 thru4, C.1 thru5, D.1 thru 4, E.1.b., E.2, and E.4.