



State of Ohio Environmental Protection Agency

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P.O. Box 1049  
Columbus, OH 43216-1049

**RE: FINAL PERMIT TO INSTALL  
MONTGOMERY COUNTY  
Application No: 08-04680  
Fac ID: 0857171794**

**CERTIFIED MAIL**

Y	TOXIC REVIEW
	PSD
Y	SYNTHETIC MINOR
	CEMS
	MACT
	NSPS
	NESHAPS
	NETTING
	MAJOR NON-ATTAINMENT
	MODELING SUBMITTED
	GASOLINE DISPENSING FACILITY

**DATE: 6/16/2005**

Eurand America Inc  
Dane Marsee  
845 Center Dr  
Vandalia, OH 45377-0000

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: 6/16/2005  
Effective Date: 6/16/2005

**FINAL PERMIT TO INSTALL 08-04680**

Application Number: 08-04680  
Facility ID: 0857171794  
Permit Fee: **\$200**  
Name of Facility: Eurand America Inc  
Person to Contact: Dane Marsee  
Address: 845 Center Dr  
Vandalia, OH 45377-0000

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

Description of proposed emissions unit(s):  
**New fluid bed coater for pharmaceuticals.**

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

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

**10. Public Disclosure**

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

**11. Applicability**

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

**12. Best Available Technology**

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

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

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

**14. Construction Compliance Certification**

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

**15. Fees**

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

**B. Permit to Install Summary of Allowable Emissions**

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

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

<u>Pollutant</u>	<u>Tons Per Year</u>
OC	2.23

**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>
P020 - Glatt Fluid Bed Coater GPCG-3 for pharmaceuticals, with catalytic oxidizer.	OAC rule 3745-31-05(A)(3)	The organic compound emissions from this emissions unit shall not exceed 0.68 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.b below.
	OAC rule 3745-35-07(B) (Synthetic Minor to avoid Title V)	The organic compound (OC) emissions from this emissions unit shall not exceed 2.23 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).

**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 Megtec catalytic oxidizer system is a common OC control device for emissions units P001, P008, P013, P014, P015, P017, P019, and P020].

- 2.b** The 0.68 pounds per hour 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. 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 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.
2. The permittee shall collect and record the following information each month:
    - a. the name and identification code of each organic solvent material employed in each batch;
    - b. the number of gallons of each organic solvent material employed in each batch;
    - c. the density of each organic solvent material employed, in pounds per gallon;
    - d. the pounds of organic solvent material employed in each batch, i.e., (b) x (c);

- e. the monthly before-control OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the summation of (d) for all batches made in P020 during the month;
  - f. the monthly controlled OC emission rate for all organic solvent materials employed, in pounds per month, i.e., the value in (e) multiplied by a factor of 1 minus the control efficiency from the most recent performance test that demonstrated compliance; and
  - g. the rolling, 12-month summation of the OC emissions from this emissions unit, in tons, i.e., the summation of (f) for the previous 12-month period divided by 2000 lbs/ton.
3. The permit to install for this emissions unit (P020) was evaluated based on the actual materials (coatings and solvent materials) and the design parameters of the emissions unit's exhaust system, as specified by the permittee in the permit to install application, for P020. 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 (ug/m<sup>3</sup>): 983,070

Maximum Hourly Emission Rate (lbs/hr): 0.68

Predicted 1-Hour Maximum Ground-Level Concentration (ug/m<sup>3</sup>): 172.8

MAGLC (ug/m<sup>3</sup>): 23,410

Physical changes to or changes in the method of operation of the emissions unit after its installation or modification could affect the parameters used to determine whether or not the "Air Toxic Policy" is satisfied. Consequently, prior to making a change that could impact such parameters, the permittee shall conduct an evaluation to determine that the "Air Toxic Policy" will still be 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 solely due to the emissions of any type of toxic air contaminant not previously emitted, and a modification of the existing permit to install will not be required, even if the toxic air contaminant emissions are greater than the de minimis level in OAC rule 3745-15-05. If the change(s) is (are) defined as a modification under other provisions of the modification definition, 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.
- 5. 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.

#### **D. Reporting Requirements**

- 1. The permittee shall submit quarterly deviation (excursion) reports, in accordance with the General Terms and Conditions of this permit, that include the following information:
  - a. 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; and

- b. an identification of each month during which the rolling, 12-month OC emission rate exceeded 2.23 tons, and the actual rolling, 12-month OC emission rate for each such month.
2. The permittee shall submit quarterly summary reports 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. 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 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 for 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, 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**

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 0.68 pound per hour (lb/hr).  
  
Applicable Compliance Method-  
Compliance shall be determined by emissions testing as specified in Section E.4 of this permit.
2. Emission Limitation-  
The organic compound (OC) emissions from this emissions unit shall not exceed 2.23 tons per rolling, 12-months  
  
Applicable Compliance Method-  
Compliance shall be determined by the record keeping as specified in Section C.2 of this permit.
3. The permittee shall conduct, or have conducted, an annual catalyst activity test on the Megtec catalytic oxidizer system in accordance with the "Megtec Catalyst Sampling and Catalyst Testing" protocol. An intent to test notification shall not be required for testing of catalyst activity.

4. 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 to demonstrate compliance with the allowable mass emission rate and overall control efficiency of 98% for organic compounds (Performance testing was performed on the Megtec catalytic oxidizer on 9/8/2004 and demonstrated a 99.7% VOC destruction efficiency.). Additional emissions testing will be addressed in the permit to operate.
  - b. 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. The capture efficiency shall be assumed to be 100%, since the unit is totally enclosed with no natural draft openings, and all emissions are vented to the catalytic oxidizer. 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.
  - c. 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.

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